Carotid Artery Stenting during Endovascular treatment of Stroke (CASES) trial

A randomized multicentre clinical trial in patients with
acute ischemic stroke and carotid artery stenosis
undergoing endovascular treatment

Case Report Forms (CRFs) ON PAPER

Version 5.0, February 2024

Study number: _____
Inclusion date (DD/MM/YY): ___/___/___

Please complete all forms as fully as possible.
Thank you for your cooperation.

Kind regards,

The CASES team
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CONTRAST
Collaboration for New Treatments of Acute Stroke

Study number: _____ Date of inclusion: ___/___/___

Checklist Inclusion and exclusion criteria

Inclusion criteria

Acute ischemic stroke due to proximal intracranial occlusion in the anterior circulation (intracranial ICA, M1, proximal M2) on the CT angiography:	o Yes	o No
Stenosis >50% according to the NASCET criteria or initial occlusion of the ipsilateral cervical carotid artery of presumed atherosclerotic origin on baseline CT angiography confirmed by digital subtraction angiography:	o Yes	o No
Eligible for EVT according to the guidelines: EVT within 6 hours of onset or EVT between 6-24 hours after onset based on perfusion CT imaging selection:	o Yes	o No
Baseline National Institute of Health Stroke Scale (NIHSS) score ≥ 2:	o Yes	o No
Age > 18 years:	o Yes	o No

If any of the inclusion criteria is answered with no, patient is not eligible for participation in the CASES trial.

Exclusion criteria

Any intracranial hemorrhage:	o Yes	o No
Cervical carotid artery stenosis or occlusion with other causes than presumed atherosclerosis (e.g., carotid artery dissection, floating thrombus, carotid web):	o Yes	o No
Any exclusion criterion for EVT according to the guidelines :	o Yes	o No
Pre stroke disability (defined as a modified Rankin Scale score >2):	o Yes	o No
Recent gastro-intestinal or urinary tract hemorrhage (<6 weeks):	o Yes	o No
Recent severe head trauma (<6 weeks) :	o Yes	o No
Recent infarction on baseline brain CT in the same vascular territory (< 6 weeks) :	o Yes	o No
Known allergy to aspirin and/or clopidogrel:	o Yes	o No
Pregnancy:	o Yes	o No

If any of the exclusion criteria is answered with yes, patient is not eligible for participation in the CASES trial.

Review all Data for this Visit

Physician
Date: ___/___/___
Signature: _____

Study Nurse
Date: ___/___/___
Signature: _____

Other, comments:_____
_____
_____
_____

Study number: _____ Date of inclusion: ___/___/___

Baseline CRF

Demographics

Age of patient at onset: _____		
Sex:	o Female	o Male

Event characteristics

Suspected location of stroke:	o Left hemisphere	o Right hemisphere
Witnessed stroke onset:	o No Date of last seen well: ___/___/____ Time of last seen well: ___:___ Date of symptoms noticed: ___/___/__ Time of symptoms noticed: ___:____	o Yes Date of symptom onset: ___/___/___ Time of symptom onset: ___:____
Transferred from primary stroke center:	o No	o Yes
If yes,	Date and time of arrival in the first hospital: ___/___/___ ___:___ Name of first hospital:_____	
Date and time arrival intervention center: ___/___/____ ___:___		
Was IV tPA administered:	o No	o Yes
If yes,	Date and Time of IVT bolus: ___/___/___ ___:___ Planned IVT dose (mg) _____mg Was the IVT pump stopped early: o No o Yes Administered IVT dose: _____ mg Reason IVT pump was stopped early: _____	

If no IV tPA administered, which contra-indications intravenous thrombolysis:

- o Time window exceeding 4,5 hours
- o Severe head trauma in past 2 months
- o Ischemic stroke in past 2 months
- o Intracranial hemorrhage in past 3 months
- o GI or urinary tract hemorrhage in past 2 weeks
- o Major surgery in past 2 weeks
- o Arterial BP ≥ 185 systolic and/or ≥110mmHg diastolic
- o Active hemorrhage/severe trauma at time of randomization
- o Use of Vit. K antagonist with INR > 1.7
- o Use of direct thrombin or factor X inhibitors
- o Use of therapeutic dose of (LMW) heparin
- o Known thrombocyte count <100*10^9/L
- o Blood glucose <2.7 or >22.0 mmol.L
- o Other, _____

(Medical) History

Atrial fibrillation or flutter:	o No	o Yes
Chronic heart failure:	o No	o Yes
Diabetes Mellitus:	o No	o Yes
Hypertension:	o No	o Yes
Hypercholesterolemia:	o No	o Yes
Intracranial hemorrhage:	o No	o Yes
Ischemic stroke:	o No	o Yes
Transient Ischemic attack:	o No	o Yes
Mech. aorta/mitral valve replacement:	o No	o Yes
Myocardial infarction:	o No	o Yes
Peripheral artery disease:	o No	o Yes
Premorbid cognitive complaints:	o No	o Yes
Falls in the past year:	o No	o Yes, number of falls:_____
Sleep apnea:	o No	o Yes

Intoxication

Smoking status:	o Never o Current: pack years_____	o Stopped < 6 months ago o Stopped > 6 months ago
Use of alcohol:	o No	o Yes; units/week_____
Use of drugs:	o No	o Yes

Study number: _____ Date of inclusion: ___/___/___

Baseline CRF

Medication (at home)

Antihypertensive drugs:	o No	o Yes
ACE-inhibitor:	o No	o Yes
Angiotensin II receptor blocker:	o No	o Yes
Beta blocker:	o No	o Yes
Calcium channel blocker:	o No	o Yes
Diuretic:	o No	o Yes
Other:	o No	o Yes
		If yes, please specify;_____
Antiplatelet agents:	o No	o Yes
Acetylsalicylic acid/carbasalate calcium:	o No	o Yes
Clopidogrel:	o No	o Yes
Dipyridamole:	o No	o Yes
Ticagrelor:	o No	o Yes
Other:	o No	o Yes
		If yes, please specify;_____
Benzodiazepine:	o No	o Yes
Vitamin K antagonist:	o No	o Yes
Acenocoumarol:	o No	o Yes
Phenprocoumon:	o No	o Yes
Direct Oral Anticoagulants:	o No	o Yes
Rivaroxaban (Xarelto):	o No	o Yes
Dabigatran (Pradaxa):	o No	o Yes
Apixaban (Eliqius):	o No	o Yes
Edoxaban (Lixiana):	o No	o Yes
Other:	o No	o Yes
		If yes, please specify;_____
Therapeutic heparin:	o No	o Yes
NSAID:	o No	o Yes
Lipid lowering therapy:	o No	o Yes
High intensity statin:	o No	o Yes
Low/moderate intensity statin:	o No	o Yes
Ezetimibe:	o No	o Yes
Fibrate:	o No	o Yes
PCSK9-inhibitor:	o No	o Yes
Other:	o No	o Yes
		If yes, please specify;_____

ⓘ High-intensity statin; Atorvastatin 40-80mg daily or Rosuvastatin 20-40mg daily

Low/moderate intensity statin: Atorvastitin 10-20mg daily, Rosuvastatin 5-10mg daily, Simvastatin 10-40mg daily, Pravastatin 10-90mg daily, Lovastatin 20-40mg daily, Fluvastatin 20-80mg daily, Pitavastatin 1-4mg daily

Anti-diabetic medication:	o No	o Yes
Insulin:	o No	o Yes
Oral antidiabetic agents:	o No	o Yes
Other:	o No	o Yes
		If yes, please specify;_____

Pre-stroke mRS

o 0: no symptoms	o 3: Moderate disability, requires assistance
o 1: minor symptoms, no limitations	o 4: Moderate severe disability
o 2: Slight disability, no help needed	o 5: Severe disability, completely dependent

Comorbidity influencing mRS:	o No	o Yes
		If yes, please specify;_____

Study number: _____ Date of inclusion: ____/____/____

Baseline CRF

Physical examination Referring center

Referral from other hospital: o Yes o No (—> intervention center)

Glasgow Coma Scale referring center total: _____/15, If available:

Eye	Motor	Verbal
o 4: Opens eyes spontaneously	o 6: Obeys commands	o 5: Oriented/converses normally
o 3: Opens eyes in response to voice	o 5: Localizes painful stimuli	o 4: Confused/disoriented
o 2: Opens eyes in resp. to pain stimuli	o 4: Flexion/withdrawal to stimuli	o 3: Utters inappropriate words
o 1: Does not open eyes	o 3: Abnormal flexion to stimuli	o 2: Incomprehensible sounds
	o 2: Extension to pain stimuli	o 1: Makes no sounds.
	o 1: Makes no movements	

Vital signs referring center: Systolic BP:_____mmHg Diastolic :_____mmHg

NIHSS referring center total: _____/42, If available:

o 1a Level of consciousness: ___(0-1-2-3)	o 4 Facial Palsy:___ (0-1-2-3)	o 7 Limb Ataxia:___ (0-1-2-9)
o 1b LOC questions: ___ (0-1-2)	o 5a Motor L arm:___ (0-1-2-3-4-9)	o 8 Sensory:___ (0-1-2)
o 1c LOC Commands: ___ (0-1-2)	o 5b Motor R arm:___ (0-1-2-3-4-9)	o 9 Best language:___ (0-1-2-3)
o 2 Best gaze: ___ (0-1-2)	o 6a Motor L leg:___ (0-1-2-3-4-9)	o 10 Dysarthria:___ (0-1-2-9)
o 3 Visual:___ (0-1-2-3)	o 6b Motor R leg:___ (0-1-2-3-4-9)	o 11Extinction & inattention:___ (0-1-2)
	If 9, please explain:	

Physical Examination Intervention center

Glasgow Coma Scale intervention center total: _____/15:

Eye	Motor	Verbal
o 4: Opens eyes spontaneously	o 6: Obeys commands	o 5: Oriented/converses normally
o 3: Opens eyes in response to voice	o 5: Localizes painful stimuli	o 4: Confused/disoriented
o 2: Opens eyes in resp. to pain stimuli	o 4: Flexion/withdrawal to stimuli	o 3: Utters inappropriate words
o 1: Does not open eyes	o 3: Abnormal flexion to stimuli	o 2: Incomprehensible sounds
	o 2: Extension to pain stimuli	o 1: Makes no sounds.
	o 1: Makes no movements	

Vital signs intervention center:

Systolic BP:_____mmHg	Diastolic BP:_____mmHg
Heart rate (bpm):_____	Height (cm):_____cm
Saturation O2: _____%	Weight (kg): _____kg
Body temperature (°C):_____°C	BMI: _____

NIHSS intervention center total: _____/42,

o 1a Level of consciousness: ___(0-1-2-3)	o 4 Facial Palsy:___ (0-1-2-3)	o 7 Limb Ataxia:___ (0-1-2-9)
o 1b LOC questions: ___ (0-1-2)	o 5a Motor L arm:___ (0-1-2-3-4-9)	o 8 Sensory:___ (0-1-2)
o 1c LOC Commands: ___ (0-1-2)	o 5b Motor R arm:___ (0-1-2-3-4-9)	o 9 Best language:___ (0-1-2-3)
o 2 Best gaze: ___ (0-1-2)	o 6a Motor L leg:___ (0-1-2-3-4-9)	o 10 Dysarthria:___ (0-1-2-9)
o 3 Visual:___ (0-1-2-3)	o 6b Motor R leg:___ (0-1-2-3-4-9)	o 11Extinction & inattention:___ (0-1-2)
	If 9, please explain:	

Laboratory results intervention center

Date of laboratory results: ___/___/___	Hemoglobin (mmol/L):_____
Time of laboratory results: ___:___	Leukocyte count (x10^9/L)_____
INR (baseline): _____	CRP (mg/L):_____
Thrombocytes (x10^9/L):_____	Serum Glucose (mmol/L): _____
APTT (sec): _____	Serum creatinine (umol/L):_____
PT (sec): _____	E-GFR (ml/min/1.73m2): _____

Please fill in with 1 decimal, e.g. 8.2mmol/L

Conversion formulas:

Thrombocyte/leukocyte count: /uL x 0.001 = x10^9 /L

Hemoglobin: g/dL x 0.6206 = mmol/L

CRP: mg/dL x 10= mg/L

Serum glucose: mg/dL x 0.0555 = mmol/L

Serum creatinine: mg/dL x 88.4=umol/L

Study number: _____ Date of inclusion: ___/___/___

Imaging

Non contrast CT scan performed at baseline:	o No (!Part of trial protocol!) Date & Time of NCCT: ___/___/___	o Yes ___:___
CT-angiography scan performed at baseline:	o No (!Part of trial protocol!) Date & Time of CTA: ___/___/___ **Side of intracranial occlusion:** o Left **Location of intracranial occlusion:** Location of target occlusion on DSA: o ICA o ICA-T o M1 o M2 proximal (temporal) o M2 distal (frontotemporal) o A1 o A2 o VA **Grading of stenosis of ICA (NASCET):** o 0-49% o 50-69% o 70-89%	o Yes ___:___ o Right o BA o P1 o P2 o Multiple distal microthrombi/emboli o Unable to determine (due to carotid artery stenosis/occlusion) o No proximal intracranial occlusion, specify; _____ o Other, _____ o ≥ 90% o Near-occlusion o Occlusion
CT perfusion scan performed at baseline:	o No Date & Time of CTP: ___/___/___	o Yes ___:___
MRI performed at baseline:	o No Date & Time of MRI: ___/___/___	o Yes ___:___
MRI-angiography scan performed at baseline:	o No Date & Time of CTA: ___/___/___ **Side of intracranial occlusion:** o Left **Location of intracranial occlusion:** Location of target occlusion on DSA: o ICA o ICA-T o M1 o M2 proximal (temporal) o M2 distal (frontotemporal) o A1 o A2 o VA **Grading of stenosis of ICA (NASCET):** o 0-49% o 50-69% o 70-89%	o Yes ___:___ o Right o BA o P1 o P2 o Multiple distal microthrombi/emboli o Unable to determine (due to carotid artery stenosis/occlusion) o No proximal intracranial occlusion, specify; _____ o Other, _____ o ≥ 90% o Near-occlusion o Occlusion

(S)AE check at baseline

Did the patient experience one or more (serious) adverse events?:	o No	o Yes **If yes, please complete SAE form(s) in Castor and report to sponsor!**

Review all Data for this Visit

Physician Date: ___/___/___ Signature: _____	Study Nurse Date: ___/___/___ Signature: _____

Other, comments:_____
_____
_____
_____

Study number: Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Timing

Date intervention:	___/___/____	Time arrival angiosuite:	___:___
Time of groin puncture:	___:___	Time recanalization (TICI >2B):	___:___
Time of sheath withdrawal/end of procedure:	___:___		

Anesthetic management

Anesthetic team present from start:	o No	o Yes
First/primary anesthetic management:	o None (local only) o Deep sedation o None + bolus short working opiates	o General anesthesia o Moderate sedation
Conversion of anesthetic management: If yes, please specify: conversion to:	o No o None (local only) o Deep sedation o None + bolus short working opiates	o Yes o General anesthesia o Moderate sedation

Moderate sedation= patient is asleep, but wakes up when spoken to or touched
Deep sedation = patients sleeps, no intubation
General anesthesia = intubation

Pre-treatment

Final BP before groin puncture:	Systolic BP:_____mmHg	Diastolic :_____mmHg
Entry location:	o A. femoralis communis o A. brachialis	o A. carotis communis o Other, _____
Entry Side:	o Left o Both	o Right
Sheath length:	☐ Short	☐ Long
Sheath size:	o 5 Fr o 6 Fr o 7 Fr o 8 Fr o 9 Fr o Other, _____	o 5 Fr o 6 Fr o 7 Fr o 8 Fr o 9 Fr o Other, _____
Grading of stenosis of cervical ICA lesion on DSA:	o 0-49% o 50-69% o 70-89%	o ≥90% o Near-occlusion o Occlusion
What is the presumed cause of the cervical carotid artery stenosis/occlusion: If other, please specify	o Atherosclerosis o Dissection o Carotid Web	o Floating Thrombus o Other: _____
Side of target occlusion on DSA:	o Left	o Right
Location of target occlusion on DSA: o ICA o ICA-T o M1 proximal o M1 distal o M2 proximal (temporal) o M2 distal (frontotemporal)	o A1 o A2 o VA o BA o P1 o P2 o Multiple distal microthrombi/emboli	o Unable to determine (due to carotid artery stenosis/occlusion) o No proximal intracranial occlusion, specify; _____ o Other, _____
Multiple locations of target occlusion:	o No	o Yes
Select all other location of target occlusion: o ICA o ICA-T o M1 proximal o M1 distal	o M2 proximal (temporal) o M2 distal (frontotemporal) o A1 o A2 o VA o BA	o P1 o P2 o Multiple distal microthrombi/emboli o Other, _____
eTICI before EVT (pre-TICI):	o 0 o 1 o 2a (<50%) o 2b (50-89%) o 2c: (90-99%) o 3	

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Number of attempts: _____

Attempt 1

Time of device attempt 1: ___:___

Target lesion/occlusion attempt 1:
- ○ ICA
- ○ ICA-T
- ○ M1 proximal
- ○ M1 distal
- ○ M2 proximal (temporal)
- ○ M2 distal (frontotemporal)
- ○ A1
- ○ A2
- ○ VA
- ○ BA
- ○ P1
- ○ P2
- ○ Multiple distal microthrombi/emboli
- ○ Unable to determine (insuff. CBF)
- ○ No proximal intracranial occlusion, specify; _____
- ○ Other, _____

Multiple locations of target occlusion: ○ No ○ Yes

Select all other multiple locations:
- ○ ICA
- ○ ICA-T
- ○ M1 proximal
- ○ M1 distal
- ○ M2 proximal (temporal)
- ○ M2 distal (frontotemporal)
- ○ A1
- ○ A2
- ○ VA
- ○ BA
- ○ P1
- ○ P2
- ○ Multiple distal microthrombi/emboli
- ○ Other, _____

What type of retriever or catheter used:

- Multiple devices possible, please fill in all devices used per attempt
- If a different device was used that is not listed above, please specify

○ **Guiding catheter**
- ☐ Arrow Sheath
- ☐ Cerebase
- ☐ AXS Infinity LS
- ☐ Other:_____

GC size:____Fr

Aspiration on guiding: ○ No ○ Yes

Aspiration technique: ○ Pump ○ Manual

○ **Distal access catheter/Aspiration catheter**
- ☐ ACE64/68/Red (Penumbra)
- ☐ 4Max (Penumbra)
- ☐ 3Max (Penumbra)
- ☐ Sofia 5F /Sofia Plus (Microvention)
- ☐ Embovac (Cerenovus)
- ☐ Catalyst (Stryker)
- ☐ AXS Vecta (Styker)
- ☐ Other: _____

DAC Size: _____Fr

Aspiration on DAC: ○ No ○ Yes

Aspiration technique: ○ Pump ○ Manual

○ **Balloon guiding catheter**
- ☐ Merci (Styker)
- ☐ Flowgate2 (Stryker)
- ☐ Cello (Medtronic)
- ☐ Other: _____

Balloon guiding catheter size:____Fr

○ **Stent retriever**
- ☐ Embotrap (Cerenovus)
- ☐ Eric (Microvention)
- ☐ Solitaire (Medtronic)
- ☐ Catch (Balt)
- ☐ Preset (Phenox)
- ☐ Trevo (Stryker)
- ☐ Tigertriever (RapidMedical)
- ☐ Nimbus (Cerenovus)
- ☐ NeVa (Vesalo)
- ☐ Other: _____

Stent retriever diameter:_____mm

Stent retriever length:_____mm

Stent at least 5 min unfolded: ○ No ○ Yes

Intra-arterial thrombolysis: ○ No ○ Yes

Thrombolysis used:
- ○ Alteplase
- ○ Urokinase
- ○ Tenecteplase
- ○ Other: _____

Dose: _____ mg or IU

eTICI score after attempt 1: ○ 0 ○ 1 ○ 2a (<50%) ○ 2b (50-89%) ○ 2c: (90-99%) ○ 3

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Number of attempts: _____

Attempt 2

Time of device attempt 2: ___:___

Target lesion/occlusion attempt 2:
- ○ ICA
- ○ ICA-T
- ○ M1 proximal
- ○ M1 distal
- ○ M2 proximal (temporal)
- ○ M2 distal (frontotemporal)
- ○ A1
- ○ A2
- ○ VA
- ○ BA
- ○ P1
- ○ P2
- ○ Multiple distal microthrombi/emboli
- ○ Unable to determine (insuff. CBF)
- ○ No proximal intracranial occlusion, specify; _____
- ○ Other, _____

Multiple locations of target occlusion: ○ No ○ Yes

Select all other multiple locations:
- ○ ICA
- ○ ICA-T
- ○ M1 proximal
- ○ M1 distal
- ○ M2 proximal (temporal)
- ○ M2 distal (frontotemporal)
- ○ A1
- ○ A2
- ○ VA
- ○ BA
- ○ P1
- ○ P2
- ○ Multiple distal microthrombi/emboli
- ○ Other, _____

What type of retriever or catheter used:
- Multiple devices possible, please fill in all devices used per attempt
- If a different device was used that is not listed above, please specify

○ **Guiding catheter**
- ☐ Arrow Sheath
- ☐ Cerebase
- ☐ AXS Infinity LS
- ☐ Other:_____

GC size:____Fr

Aspiration on guiding: ○ No ○ Yes

Aspiration technique: ○ Pump ○ Manual

○ **Distal access catheter/Aspiration catheter**
- ☐ ACE64/68/Red (Penumbra)
- ☐ 4Max (Penumbra)
- ☐ 3Max (Penumbra)
- ☐ Sofia 5F /Sofia Plus (Microvention)
- ☐ Embovac (Cerenovus)
- ☐ Catalyst (Stryker)
- ☐ AXS Vecta (Styker)
- ☐ Other: _____

DAC Size: _____Fr

Aspiration on DAC: ○ No ○ Yes

Aspiration technique: ○ Pump ○ Manual

○ **Balloon guiding catheter**
- ☐ Merci (Styker)
- ☐ Flowgate2 (Stryker)
- ☐ Cello (Medtronic)
- ☐ Other: _____

Balloon guiding catheter size:____Fr

○ **Stent retriever**
- ☐ Embotrap (Cerenovus)
- ☐ Eric (Microvention)
- ☐ Solitaire (Medtronic)
- ☐ Catch (Balt)
- ☐ Preset (Phenox)
- ☐ Trevo (Stryker)
- ☐ Tigertriever (RapidMedical)
- ☐ Nimbus (Cerenovus)
- ☐ NeVa (Vesalo)
- ☐ Other: _____

Stent retriever diameter:_____mm

Stent retriever length:_____mm

Stent at least 5 min unfolded: ○ No ○ Yes

Intra-arterial thrombolysis: ○ No ○ Yes

Thrombolysis used:
- ○ Alteplase
- ○ Urokinase
- ○ Tenecteplase
- ○ Other: _____

Dose: _____ mg or IU

eTICI score after attempt 2: ○ 0 ○ 1 ○ 2a (<50%) ○ 2b (50-89%) ○ 2c: (90-99%) ○ 3

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Number of attempts: _____

Attempt 3

Time of device attempt 3: ___:___

Target lesion/occlusion attempt 3:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Unable to determine (insuff. CBF)
- o No proximal intracranial occlusion, specify; _____
- o Other, _____

Multiple locations of target occlusion: o No o Yes

Select all other multiple locations:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Other, _____

What type of retriever or catheter used:
- Multiple devices possible, please fill in all devices used per attempt
- If a different device was used that is not listed above, please specify

o **Guiding catheter**
- ☐ Arrow Sheath
- ☐ Cerebase
- ☐ AXS Infinity LS
- ☐ Other:_____

GC size:____Fr

Aspiration on guiding: o No o Yes

Aspiration technique: o Pump o Manual

o **Distal access catheter/Aspiration catheter**
- ☐ ACE64/68/Red (Penumbra)
- ☐ 4Max (Penumbra)
- ☐ 3Max (Penumbra)
- ☐ Sofia 5F /Sofia Plus (Microvention)
- ☐ Embovac (Cerenovus)
- ☐ Catalyst (Stryker)
- ☐ AXS Vecta (Styker)
- ☐ Other: _____

DAC Size: _____Fr

Aspiration on DAC: o No o Yes

Aspiration technique: o Pump o Manual

o **Balloon guiding catheter**
- ☐ Merci (Styker)
- ☐ Flowgate2 (Stryker)
- ☐ Cello (Medtronic)
- ☐ Other: _____

Balloon guiding catheter size:____Fr

o **Stent retriever**
- ☐ Embotrap (Cerenovus)
- ☐ Eric (Microvention)
- ☐ Solitaire (Medtronic)
- ☐ Catch (Balt)
- ☐ Preset (Phenox)
- ☐ Trevo (Stryker)
- ☐ Tigertriever (RapidMedical)
- ☐ Nimbus (Cerenovus)
- ☐ NeVa (Vesalo)
- ☐ Other: _____

Stent retriever diameter:_____mm

Stent retriever length:_____mm

Stent at least 5 min unfolded: o No o Yes

Intra-arterial thrombolysis: o No o Yes

Thrombolysis used:
- o Alteplase
- o Urokinase
- o Tenecteplase
- o Other: _____

Dose: _____ mg or IU

eTICI score after attempt 3: o 0 o 1 o 2a (<50%) o 2b (50-89%) o 2c: (90-99%) o 3

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Number of attempts: _____

Attempt 4

Time of device attempt 4: ___:___

Target lesion/occlusion attempt 4:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Unable to determine (insuff. CBF)
- o No proximal intracranial occlusion, specify; _____
- o Other, _____

Multiple locations of target occlusion: o No o Yes

Select all other multiple locations:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Other, _____

What type of retriever or catheter used:
- *Multiple devices possible, please fill in all devices used per attempt*
- *If a different device was used that is not listed above, please specify*

o **Guiding catheter**
- ☐ Arrow Sheath
- ☐ Cerebase
- ☐ AXS Infinity LS
- ☐ Other:_____

GC size:____Fr

Aspiration on guiding: o No o Yes

Aspiration technique: o Pump o Manual

o **Distal access catheter/Aspiration catheter**
- ☐ ACE64/68/Red (Penumbra)
- ☐ 4Max (Penumbra)
- ☐ 3Max (Penumbra)
- ☐ Sofia 5F /Sofia Plus (Microvention)
- ☐ Embovac (Cerenovus)
- ☐ Catalyst (Stryker)
- ☐ AXS Vecta (Styker)
- ☐ Other: _____

DAC Size: _____Fr

Aspiration on DAC: o No o Yes

Aspiration technique: o Pump o Manual

o **Balloon guiding catheter**
- ☐ Merci (Styker)
- ☐ Flowgate2 (Stryker)
- ☐ Cello (Medtronic)
- ☐ Other: _____

Balloon guiding catheter size:____Fr

o **Stent retriever**
- ☐ Embotrap (Cerenovus)
- ☐ Eric (Microvention)
- ☐ Solitaire (Medtronic)
- ☐ Catch (Balt)
- ☐ Preset (Phenox)
- ☐ Trevo (Stryker)
- ☐ Tigertriever (RapidMedical)
- ☐ Nimbus (Cerenovus)
- ☐ NeVa (Vesalo)
- ☐ Other: _____

Stent retriever diameter:_____mm

Stent retriever length:_____mm

Stent at least 5 min unfolded: o No o Yes

Intra-arterial thrombolysis: o No o Yes

Thrombolysis used:
- o Alteplase
- o Urokinase
- o Tenecteplase
- o Other: _____

Dose: _____ mg or IU

eTICI score after attempt 4: o 0 o 1 o 2a (<50%) o 2b (50-89%) o 2c: (90-99%) o 3

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Number of attempts: _____

Attempt 5

Time of device attempt 5: ___:___

Target lesion/occlusion attempt 5:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Unable to determine (insuff. CBF)
- o No proximal intracranial occlusion, specify; _____
- o Other, _____

Multiple locations of target occlusion: o No o Yes

Select all other multiple locations:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Other, _____

What type of retriever or catheter used:
- *Multiple devices possible, please fill in all devices used per attempt*
- *If a different device was used that is not listed above, please specify*

o **Guiding catheter**
- ☐ Arrow Sheath
- ☐ Cerebase
- ☐ AXS Infinity LS
- ☐ Other:_____

GC size:____Fr

Aspiration on guiding: o No o Yes

Aspiration technique: o Pump o Manual

o **Distal access catheter/Aspiration catheter**
- ☐ ACE64/68/Red (Penumbra)
- ☐ 4Max (Penumbra)
- ☐ 3Max (Penumbra)
- ☐ Sofia 5F /Sofia Plus (Microvention)
- ☐ Embovac (Cerenovus)
- ☐ Catalyst (Stryker)
- ☐ AXS Vecta (Styker)
- ☐ Other: _____

DAC Size: _____Fr

Aspiration on DAC: o No o Yes

Aspiration technique: o Pump o Manual

o **Balloon guiding catheter**
- ☐ Merci (Styker)
- ☐ Flowgate2 (Stryker)
- ☐ Cello (Medtronic)
- ☐ Other: _____

Balloon guiding catheter size:____Fr

o **Stent retriever**
- ☐ Embotrap (Cerenovus)
- ☐ Eric (Microvention)
- ☐ Solitaire (Medtronic)
- ☐ Catch (Balt)
- ☐ Preset (Phenox)
- ☐ Trevo (Stryker)
- ☐ Tigertriever (RapidMedical)
- ☐ Nimbus (Cerenovus)
- ☐ NeVa (Vesalo)
- ☐ Other: _____

Stent retriever diameter:_____mm

Stent retriever length:_____mm

Stent at least 5 min unfolded: o No o Yes

Intra-arterial thrombolysis: o No o Yes

Thrombolysis used:
- o Alteplase
- o Urokinase
- o Tenecteplase
- o Other: _____

Dose: _____ mg or IU

eTICI score after attempt 5: o 0 o 1 o 2a (<50%) o 2b (50-89%) o 2c: (90-99%) o 3

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Number of attempts: _____

Attempt 6

Time of device attempt 6: ___:___

Target lesion/occlusion attempt 6:
- ○ ICA
- ○ ICA-T
- ○ M1 proximal
- ○ M1 distal
- ○ M2 proximal (temporal)
- ○ M2 distal (frontotemporal)
- ○ A1
- ○ A2
- ○ VA
- ○ BA
- ○ P1
- ○ P2
- ○ Multiple distal microthrombi/emboli
- ○ Unable to determine (insuff. CBF)
- ○ No proximal intracranial occlusion, specify; _____
- ○ Other, _____

Multiple locations of target occlusion: ○ No ○ Yes

Select all other multiple locations:
- ○ ICA
- ○ ICA-T
- ○ M1 proximal
- ○ M1 distal
- ○ M2 proximal (temporal)
- ○ M2 distal (frontotemporal)
- ○ A1
- ○ A2
- ○ VA
- ○ BA
- ○ P1
- ○ P2
- ○ Multiple distal microthrombi/emboli
- ○ Other, _____

What type of retriever or catheter used:
- Multiple devices possible, please fill in all devices used per attempt
- If a different device was used that is not listed above, please specify

○ **Guiding catheter**
- ☐ Arrow Sheath
- ☐ Cerebase
- ☐ AXS Infinity LS
- ☐ Other:_____

GC size:____Fr

Aspiration on guiding: ○ No ○ Yes

Aspiration technique: ○ Pump ○ Manual

○ **Distal access catheter/Aspiration catheter**
- ☐ ACE64/68/Red (Penumbra)
- ☐ 4Max (Penumbra)
- ☐ 3Max (Penumbra)
- ☐ Sofia 5F /Sofia Plus (Microvention)
- ☐ Embovac (Cerenovus)
- ☐ Catalyst (Stryker)
- ☐ AXS Vecta (Styker)
- ☐ Other: _____

DAC Size: _____Fr

Aspiration on DAC: ○ No ○ Yes

Aspiration technique: ○ Pump ○ Manual

○ **Balloon guiding catheter**
- ☐ Merci (Styker)
- ☐ Flowgate2 (Stryker)
- ☐ Cello (Medtronic)
- ☐ Other: _____

Balloon guiding catheter size:____Fr

○ **Stent retriever**
- ☐ Embotrap (Cerenovus)
- ☐ Eric (Microvention)
- ☐ Solitaire (Medtronic)
- ☐ Catch (Balt)
- ☐ Preset (Phenox)
- ☐ Trevo (Stryker)
- ☐ Tigertriever (RapidMedical)
- ☐ Nimbus (Cerenovus)
- ☐ NeVa (Vesalo)
- ☐ Other: _____

Stent retriever diameter:_____mm

Stent retriever length:_____mm

Stent at least 5 min unfolded: ○ No ○ Yes

Intra-arterial thrombolysis: ○ No ○ Yes

Thrombolysis used:
- ○ Alteplase
- ○ Urokinase
- ○ Tenecteplase
- ○ Other: _____

Dose: _____ mg or IU

eTICI score after attempt 6: ○ 0 ○ 1 ○ 2a (<50%) ○ 2b (50-89%) ○ 2c: (90-99%) ○ 3

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Number of attempts: _____

Attempt 7

Time of device attempt 7: ___:___

Target lesion/occlusion attempt 7:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Unable to determine (insuff. CBF)
- o No proximal intracranial occlusion, specify; _____
- o Other, _____

Multiple locations of target occlusion: o No o Yes

Select all other multiple locations:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Other, _____

What type of retriever or catheter used:
- *Multiple devices possible, please fill in all devices used per attempt*
- *If a different device was used that is not listed above, please specify*

o **Guiding catheter**
- ☐ Arrow Sheath
- ☐ Cerebase
- ☐ AXS Infinity LS
- ☐ Other:_____

GC size:____Fr

Aspiration on guiding: o No o Yes

Aspiration technique: o Pump o Manual

o **Distal access catheter/Aspiration catheter**
- ☐ ACE64/68/Red (Penumbra)
- ☐ 4Max (Penumbra)
- ☐ 3Max (Penumbra)
- ☐ Sofia 5F /Sofia Plus (Microvention)
- ☐ Embovac (Cerenovus)
- ☐ Catalyst (Stryker)
- ☐ AXS Vecta (Styker)
- ☐ Other: _____

DAC Size: _____Fr

Aspiration on DAC: o No o Yes

Aspiration technique: o Pump o Manual

o **Balloon guiding catheter**
- ☐ Merci (Styker)
- ☐ Flowgate2 (Stryker)
- ☐ Cello (Medtronic)
- ☐ Other: _____

Balloon guiding catheter size:____Fr

o **Stent retriever**
- ☐ Embotrap (Cerenovus)
- ☐ Eric (Microvention)
- ☐ Solitaire (Medtronic)
- ☐ Catch (Balt)
- ☐ Preset (Phenox)
- ☐ Trevo (Stryker)
- ☐ Tigertriever (RapidMedical)
- ☐ Nimbus (Cerenovus)
- ☐ NeVa (Vesalo)
- ☐ Other: _____

Stent retriever diameter:_____mm

Stent retriever length:_____mm

Stent at least 5 min unfolded: o No o Yes

Intra-arterial thrombolysis: o No o Yes

Thrombolysis used:
- o Alteplase
- o Urokinase
- o Tenecteplase
- o Other: _____

Dose: _____ mg or IU

eTICI score after attempt 7: o 0 o 1 o 2a (<50%) o 2b (50-89%) o 2c: (90-99%) o 3

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Number of attempts: _____

Attempt 8

Time of device attempt 8: ___:___

Target lesion/occlusion attempt 8:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Unable to determine (insuff. CBF)
- o No proximal intracranial occlusion, specify; _____
- o Other, _____

Multiple locations of target occlusion: o No o Yes

Select all other multiple locations:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Other, _____

What type of retriever or catheter used:
- *Multiple devices possible, please fill in all devices used per attempt*
- *If a different device was used that is not listed above, please specify*

o **Guiding catheter**
- ☐ Arrow Sheath
- ☐ Cerebase
- ☐ AXS Infinity LS
- ☐ Other:_____

GC size:____Fr

Aspiration on guiding: o No o Yes

Aspiration technique: o Pump o Manual

o **Distal access catheter/Aspiration catheter**
- ☐ ACE64/68/Red (Penumbra)
- ☐ 4Max (Penumbra)
- ☐ 3Max (Penumbra)
- ☐ Sofia 5F /Sofia Plus (Microvention)
- ☐ Embovac (Cerenovus)
- ☐ Catalyst (Stryker)
- ☐ AXS Vecta (Styker)
- ☐ Other: _____

DAC Size: _____Fr

Aspiration on DAC: o No o Yes

Aspiration technique: o Pump o Manual

o **Balloon guiding catheter**
- ☐ Merci (Styker)
- ☐ Flowgate2 (Stryker)
- ☐ Cello (Medtronic)
- ☐ Other: _____

Balloon guiding catheter size:____Fr

o **Stent retriever**
- ☐ Embotrap (Cerenovus)
- ☐ Eric (Microvention)
- ☐ Solitaire (Medtronic)
- ☐ Catch (Balt)
- ☐ Preset (Phenox)
- ☐ Trevo (Stryker)
- ☐ Tigertriever (RapidMedical)
- ☐ Nimbus (Cerenovus)
- ☐ NeVa (Vesalo)
- ☐ Other: _____

Stent retriever diameter:_____mm

Stent retriever length:_____mm

Stent at least 5 min unfolded: o No o Yes

Intra-arterial thrombolysis: o No o Yes

Thrombolysis used:
- o Alteplase
- o Urokinase
- o Tenecteplase
- o Other: _____

Dose: _____ mg or IU

eTICI score after attempt 8: o 0 o 1 o 2a (<50%) o 2b (50-89%) o 2c: (90-99%) o 3

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Number of attempts: _____

Attempt 9

Time of device attempt 9: ___:___

Target lesion/occlusion attempt 9:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Unable to determine (insuff. CBF)
- o No proximal intracranial occlusion, specify; _____
- o Other, _____

Multiple locations of target occlusion: o No o Yes

Select all other multiple locations:
- o ICA
- o ICA-T
- o M1 proximal
- o M1 distal
- o M2 proximal (temporal)
- o M2 distal (frontotemporal)
- o A1
- o A2
- o VA
- o BA
- o P1
- o P2
- o Multiple distal microthrombi/emboli
- o Other, _____

What type of retriever or catheter used:
- Multiple devices possible, please fill in all devices used per attempt
- If a different device was used that is not listed above, please specify

o **Guiding catheter**
- ☐ Arrow Sheath
- ☐ Cerebase
- ☐ AXS Infinity LS
- ☐ Other:_____

GC size:____Fr

Aspiration on guiding: o No o Yes

Aspiration technique: o Pump o Manual

o **Distal access catheter/Aspiration catheter**
- ☐ ACE64/68/Red (Penumbra)
- ☐ 4Max (Penumbra)
- ☐ 3Max (Penumbra)
- ☐ Sofia 5F /Sofia Plus (Microvention)
- ☐ Embovac (Cerenovus)
- ☐ Catalyst (Stryker)
- ☐ AXS Vecta (Styker)
- ☐ Other: _____

DAC Size: _____Fr

Aspiration on DAC: o No o Yes

Aspiration technique: o Pump o Manual

o **Balloon guiding catheter**
- ☐ Merci (Styker)
- ☐ Flowgate2 (Stryker)
- ☐ Cello (Medtronic)
- ☐ Other: _____

Balloon guiding catheter size:____Fr

o **Stent retriever**
- ☐ Embotrap (Cerenovus)
- ☐ Eric (Microvention)
- ☐ Solitaire (Medtronic)
- ☐ Catch (Balt)
- ☐ Preset (Phenox)
- ☐ Trevo (Stryker)
- ☐ Tigertriever (RapidMedical)
- ☐ Nimbus (Cerenovus)
- ☐ NeVa (Vesalo)
- ☐ Other: _____

Stent retriever diameter:_____mm

Stent retriever length:_____mm

Stent at least 5 min unfolded: o No o Yes

Intra-arterial thrombolysis: o No o Yes

Thrombolysis used:
- o Alteplase
- o Urokinase
- o Tenecteplase
- o Other: _____

Dose: _____ mg or IU

eTICI score after attempt 9: o 0 o 1 o 2a (<50%) o 2b (50-89%) o 2c: (90-99%) o 3

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Number of attempts: _____

Attempt 10

Time of device attempt 10: ___:___

Target lesion/occlusion attempt 10:

- ○ ICA
- ○ ICA-T
- ○ M1 proximal
- ○ M1 distal
- ○ M2 proximal (temporal)
- ○ M2 distal (frontotemporal)
- ○ A1
- ○ A2
- ○ VA
- ○ BA
- ○ P1
- ○ P2
- ○ Multiple distal microthrombi/emboli
- ○ Unable to determine (insuff. CBF)
- ○ No proximal intracranial occlusion, specify; _____
- ○ Other, _____

Multiple locations of target occlusion: ○ No ○ Yes

Select all other multiple locations:

- ○ ICA
- ○ ICA-T
- ○ M1 proximal
- ○ M1 distal
- ○ M2 proximal (temporal)
- ○ M2 distal (frontotemporal)
- ○ A1
- ○ A2
- ○ VA
- ○ BA
- ○ P1
- ○ P2
- ○ Multiple distal microthrombi/emboli
- ○ Other, _____

What type of retriever or catheter used:

- Multiple devices possible, please fill in all devices used per attempt
- If a different device was used that is not listed above, please specify

○ **Guiding catheter**

- ☐ Arrow Sheath
- ☐ Cerebase
- ☐ AXS Infinity LS
- ☐ Other:_____

GC size:____Fr

Aspiration on guiding: ○ No ○ Yes

Aspiration technique: ○ Pump ○ Manual

○ **Distal access catheter/Aspiration catheter**

- ☐ ACE64/68/Red (Penumbra)
- ☐ 4Max (Penumbra)
- ☐ 3Max (Penumbra)
- ☐ Sofia 5F /Sofia Plus (Microvention)
- ☐ Embovac (Cerenovus)
- ☐ Catalyst (Stryker)
- ☐ AXS Vecta (Styker)
- ☐ Other: _____

DAC Size: _____Fr

Aspiration on DAC: ○ No ○ Yes

Aspiration technique: ○ Pump ○ Manual

○ **Balloon guiding catheter**

- ☐ Merci (Styker)
- ☐ Flowgate2 (Stryker)
- ☐ Cello (Medtronic)
- ☐ Other: _____

Balloon guiding catheter size:____Fr

○ **Stent retriever**

- ☐ Embotrap (Cerenovus)
- ☐ Eric (Microvention)
- ☐ Solitaire (Medtronic)
- ☐ Catch (Balt)
- ☐ Preset (Phenox)
- ☐ Trevo (Stryker)
- ☐ Tigertriever (RapidMedical)
- ☐ Nimbus (Cerenovus)
- ☐ NeVa (Vesalo)
- ☐ Other: _____

Stent retriever diameter:_____mm

Stent retriever length:_____mm

Stent at least 5 min unfolded: ○ No ○ Yes

Intra-arterial thrombolysis: ○ No ○ Yes

Thrombolysis used:

- ○ Alteplase
- ○ Urokinase
- ○ Tenecteplase
- ○ Other: _____

Dose: _____ mg or IU

eTICI score after attempt 10: ○ 0 ○ 1 ○ 2a (<50%) ○ 2b (50-89%) ○ 2c: (90-99%) ○ 3

Study number: _____ Date of inclusion: ___/___/___

ENDOVASCULAR TREATMENT CRF

Treatment

Performed procedure:	○ Catheterization only ○ Cerebral DSA only ○ EVT	○ Other, _____ ○ No procedure performed, please explain:_____
Was PTA performed in ICA:	○ No	○ Yes
When was PTA performed:	○ Before intracranial thrombus removal ○ After intracranial thrombus removal	○ Both
Balloon dimensions:	Length: _____mm	Diameter:_____mm
Intracranial cerebral DSA performed in 2 directions:	○ No	○ Yes
Extracranial carotid DSA performed in 2 directions:	○ No	○ Yes

Final eTICI after EVT (post-TICI): ○ 0 ○ 1 ○ 2a (<50%) ○ 2b (50-89%) ○ 2c: (90-99%) ○ 3

Procedural complications:	○ No	○ Yes
Which complication(s):	○ Distal thrombus ○ Dissection ○ Embolization in new territory	○ Perforation ○ Significant flow-limiting vasospasms ○ Other, _____

Please specify location of complication(s);_____

Remarks EVT;_____

Periprocedural medication:	○ Heparin	Total dose:_____ IU
	○ Tirofiban (Aggrastat)	Total dose:_____ mcg
	○ Eptifibatide (Integrilin)	Total dose:_____ mg
	○ Acetylsalicylic acid (Aspegic)	Total dose:_____ mg
	○ Clopidogrel	Total dose:_____ mg
	○ Nimodipine	Total dose:_____ mg
	○ Other, _____	Total dose:_____
	○ No periprocedural medication given	

(S)AE Check after EVT

Did the patient experience one or more (serious) adverse events during EVT?:	○ No	○ Yes **If yes, please complete SAE form(s) in Castor and report to sponsor!**

Review all Data for this Visit

Physician Date: ___/___/___ Signature: _____	Study Nurse Date: ___/___/___ Signature: _____

Other, comments:_____

_____

_____

_____

Study number: _____ Date of inclusion: ___/___/___

STUDY TREATMENT CRF

Study Treatment

Was immediate CAS performed:	o No	o Yes
If crossover; what was the reason: _____		
	Report crossover to sponsor!	
Was CAS performed prior to thrombectomy:	o No (retrograde)	o Yes (antegrade)
When did PTA take place?	o Before stent placement o After stent placement	o Both before and after stent placement o No PTA performed
Balloon measurements:	Diameter:_____mm	Length:_____mm
Time of stent placement: ___:___		
What was the type of stent used? If other, please specify (Multiple options possible)	o Roadsaver (Terumo) o Casper (Microvention) o CGuard (Inspire MD) o Wallstent (Boston Scientific o Xact (Abbott)	o Acculink (Abbott) o NexStent (EndoTex) o Protégé RX (Medtronic) o Precise Pro Rx (Cordis) o Other: _____
Stent measurements:	Length:_____mm	Diameter:_____mm
Was a cerebral protection device used during EVT:	o No	o Yes
If yes, what type of cerebral perfusion protection was used:	o Proximal protection device Please specify:_____	o Distal protection device
Did the patient receive a loading dose of IV aspirin 500mg during or shortly after the CAS (within 1 hour of groin closure):	o No If no, please specify:_____	o Yes
Did any of the following events occur during the procedure: (multiple options possible)	o Bradycardia o Hypotension o Carotid stent thrombosis o Embolization in new vascular territories o None of the above	
If carotid stent thrombosis, which antiplatelet medication was administered:	o None o Tirofiban (Aggrastat)	o Eptifibatide (Integrilin) o Other, _____
Total dose antiplatelet medication: _____mcg		

(S)AE Check after study treatment

Did the patient experience one of more (serious) adverse events:	o No	o Yes
	If yes, please complete (S)AE form(s) in Castor and report to sponsor!	

Review all Data for this Visit

Physician Date: ___/___/___ Signature: _____	Study Nurse Date: ___/___/___ Signature: _____

Other, comments:_____
_____
_____
_____

Study number: _____ Date of inclusion: ___/___/___

DEFERRED TREATMENT CRF

Where was the decision regarding the deferred treatment strategy made:	o Intervention center o Referring center	o Other, _____
What was the deferred treatment strategy:	o Carotid Endarterectomy (CEA) o Best medical therapy o Carotid artery stenting (CAS)	

General procedure information

Date and time of procedure:	___/___/___ ___:___	
Carotid artery treated:	o Left	o Right

Anticoagulation/antiplatelet therapy (multiple options possible):

Preprocedural: started on ward before procedure, During procedure: administered in anesthetic room or angiography suite, Post-procedural: Given on ward immediately after procedure.

Pre-procedural:	During procedure:	Post-procedural:
o Aspirin	o Aspirin	o Aspirin
o Dipyramidole	o Dipyramidole	o Dipyramidole
o Clopidogrel	o Clopidogrel	o Clopidogrel
o Ticlodopine	o Ticlodopine	o Ticlodopine
o Warfarin	o Warfarin	o Warfarin
o Heparin or LMWH (therapeutic dose)	o Heparin or LMWH (therapeutic dose)	o Heparin or LMWH (therapeutic dose)
o Heparin or LMWH (prophylactic dose)	o Heparin or LMWH (prophylactic dose)	o Heparin or LMWH (prophylactic dose)
o Other antithrombotic; _____	o Other antithrombotic; _____	o Other antithrombotic; _____

Carotid Endarterectomy

Duration of procedure:	___:___	
Type of anesthetic used:	o General anesthesia o Local/Regional anesthesia o Combined local/regional and general anesthesia	
Type of reconstruction used:	o Standard endarterectomy o Eversion endarterectomy o Vein interposition	
Was a shunt used:	o No	o Yes
Occlusion time:	___:___	(Do not include shunt time if used)
Was intra-operative neuromonitoring performed?	o EEG o Transcranial doppler (TCD) o EEG + TCD o No intra-operative neuromonitoring performed	
Did the patient experience one or more (serious) adverse events during CEA:	o No	o Yes **If yes, please complete (S)AE form(s) in Castor and report to sponsor!**

Best medical therapy

What was the reason this option was chosen:	o Patient did not recover well from stroke o Patient did not consent to intervention o Patient did not have high grade stenosis o There was no carotid stenosis/occlusion left after EVT o During follow-up, there was a complete carotid artery occlusion o Other, please specify: _____

Study number: _____ Date of inclusion: ___/___/___

DEFERRED TREATMENT CRF

Carotid Artery Stenting

What was the reason this option was chosen: _____		
Duration of procedure:	___:___	
Anesthetic management:	o None (local only) o None + bolus short working opiates o Moderate sedation	o Deep sedation o General anesthesia

Moderate sedation= patient is asleep, but wakes up when spoken to or touched
Deep sedation = patients sleeps, no intubation
General anesthesia = intubation

Was PTA performed, and if so when:	o PTA performed before CAS o PTA performed after CAS	o PTA both before and after CAS o No PTA performed
Balloon measurements:	Diameter:_____mm	Length:_____mm
What was the type of stent used? If other, please specify (Multiple options possible)	o Roadsaver (Terumo) o Casper (Microvention) o CGuard (Inspire MD) o Wallstent (Boston Scientific o Xact (Abbott)	o Acculink (Abbott) o NexStent (EndoTex) o Protégé RX (Medtronic) o Precise Pro Rx (Cordis) o Other: _____
Stent measurements:	Diameter:_____mm	Length:_____mm
Was the stent successfully deployed:	o No	o Yes
Was a cerebral protection device used during CAS?	o No	o Yes
If yes, what type of cerebral perfusion protection was used:	o Proximal protection device Please specify: _____	o Distal protection device
Did any of the following events occur during the procedure:	o Bradycardia o Hypotension o Carotid stent thrombosis o Embolization in new vascular territories o None of the above	
If carotid stent thrombosis, was escape medication (tirofiban [Aggrastat] bolus 25microg/kg followed by 0,15microg/kg/min) used: administered:	o No	o Yes
Did the patient experience one or more (serious) adverse events during CAS:	o No	o Yes **If yes, please complete (S)AE form(s) in Castor and report to sponsor!**

Review all Data for this Visit

Physician Date: ___/___/___ Signature: _____	Study Nurse Date: ___/___/___ Signature: _____

Other, comments:_____
_____
_____
_____

Study number: _____ Date of inclusion: ___/___/___

24 hours follow-up CRF

NIHSS

Date of NIHSS at 24h: ___/___/____

NIHSS total: _____/42,

- o 1a Level of consciousness: ___(0-1-2-3)
- o 1b LOC questions: ___ (0-1-2)
- o 1c LOC Commands: ___ (0-1-2)
- o 2 Best gaze: ___ (0-1-2)
- o 3 Visual:___ (0-1-2-3)
- o 4 Facial Palsy:___ (0-1-2-3)
- o 5a Motor L arm:___ (0-1-2-3-4-9)
- o 5b Motor R arm:___ (0-1-2-3-4-9)
- o 6a Motor L leg:___ (0-1-2-3-4-9)
- o 6b Motor R leg:___ (0-1-2-3-4-9)

If 9, please explain:

- o 7 Limb Ataxia:___ (0-1-2-9)
- o 8 Sensory:___ (0-1-2)
- o 9 Best language:___ (0-1-2-3)
- o 10 Dysarthria:___ (0-1-2-9)
- o 11Extinction & inattention:___ (0-1-2)

(S)AE Check after 24 hours

Was there evidence for any of the following:

- o Symptomatic intracerebral hemorrhage
- o Asymptomatic intracerebral hemorrhage
- o Extracranial hemorrhage
- o Embolization in new vascular territories
- o Complications at the vascular access site
- o No

Symptomatic intracranial hemorrhage = a new intracranial hemorrhage associated with any of the following:

- o ≥4 point increase in NIHSS
- o ≥ 2 point increase in one NIHSS subcategory
- o leading to major medical/surgical intervention such as intubation, hemicraniectomy, or ventricular drain placement
- o absence of an alternative explanation for deterioration

If complications at the vascular access site within 72 hours after the intervention which:

- o Aneurysm
- o Bleeding
- o Vascular occlusion

Did the patient experience one or more (serious) adverse events: o No o Yes

If yes, please complete (S)AE form(s) in Castor and report to sponsor!

Imaging

Non contrast CT scan performed at 24 hours: o No (!Part of trial protocol!) o Yes

Date & Time of NCCT: ___/___/___ ___:___

CT-angiography scan performed at 24 hours: o No (!Part of trial protocol!) o Yes

Date & Time of CTA: ___/___/___ ___:___

If no, please specify:_____

What alternative imaging was performed: o MRA o Carotid duplex ultrasound o DSA o Other, _____ o No alternative imaging performed

Date & Time of alternative imaging: ___/___/____ ___:___

Is there carotid re-occlusion at 24 hours: o No o Yes

Review all Data for this Visit

Physician
Date: ___/___/___
Signature: _____

Study Nurse
Date: ___/___/___
Signature: _____

Other, comments:_____
_____
_____
_____

Study number: _____ Date of inclusion: ___/___/___

6 ± 1 day follow-up CRF

Day 6±1 assessment performed in: ○ Intervention center ○ Second hospital (transfer)

NIHSS

Date of NIHSS at 6 ± 1 days: ___/___/____

NIHSS total: _____/42,

○ 1a Level of consciousness: ___(0-1-2-3)	○ 4 Facial Palsy:___ (0-1-2-3)	○ 7 Limb Ataxia:___ (0-1-2-9)
○ 1b LOC questions: ___ (0-1-2)	○ 5a Motor L arm:___ (0-1-2-3-4-9)	○ 8 Sensory:___ (0-1-2)
○ 1c LOC Commands: ___ (0-1-2)	○ 5b Motor R arm:___ (0-1-2-3-4-9)	○ 9 Best language:___ (0-1-2-3)
○ 2 Best gaze: ___ (0-1-2)	○ 6a Motor L leg:___ (0-1-2-3-4-9)	○ 10 Dysarthria:___ (0-1-2-9)
○ 3 Visual:___ (0-1-2-3)	○ 6b Motor R leg:___ (0-1-2-3-4-9)	○ 11Extinction & inattention:___ (0-1-2)
	If 9, please explain:	

(S)AE check at 6 ± 1 day

Was there evidence for any of the following:	○ Symptomatic intracerebral hemorrhage ○ Asymptomatic intracerebral hemorrhage ○ Extracranial hemorrhage ○ Embolization in new vascular territories ○ Complications at the vascular access site ○ No

Symptomatic intracranial hemorrhage = a new intracranial hemorrhage associated with any of the following:
- ○ ≥4 point increase in NIHSS
- ○ ≥ 2 point increase in one NIHSS subcategory
- ○ leading to major medical/surgical intervention such as intubation, hemicraniectomy, or ventricular drain placement
- ○ absence of an alternative explanation for deterioration

If complications at the vascular access site within 72 hours after the intervention, which:	○ Aneurysm ○ Bleeding ○ Vascular occlusion
Did the patient experience one or more (serious) adverse events:	○ No ○ Yes **If yes, please complete SAE form(s) in Castor and report to sponsor!**

Review all Data for this Visit

Physician Date: ___/___/___ Signature: _____	Study Nurse Date: ___/___/___ Signature: _____

Other, comments:_____
_____
_____
_____

Study number: _____ Date of inclusion: ___/___/___

DISCHARGE INTERVENTION CENTER CRF

Neuroimaging—Intervention center

Any additional neuroimaging performed during hospital stay (excl. study imaging):	○ No	○ Yes Send all neuroimaging performed during admission to the study team.

Medication during hospital stay—Intervention center

Antiplatelet agents:	○ No	○ Yes
Acetylsalicylic acid/carbasalate calcium:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Clopidogrel:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Dipyridamole:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Ticagrelor:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Other:	○ No Start: ___/___/___	○ Yes If yes, please specify;_____ Stop (if applicable): ___/___/___
Direct Oral Anticoagulants:	○ No	○ Yes
Apixaban (Eliquis):	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Dabigatran (Pradaxa):	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Edoxaban (Lixiana):	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Rivaroxaban (Xarelto):	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Other, _____	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Vitamin K antagonist:	○ No	○ Yes
Acenocoumarol:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Phenprocoumon:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Heparin:	○ No	○ Yes
Prophylactic heparin:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Therapeutic heparin:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Other anticoagulants:	○ No Start: ___/___/___	○ Yes If yes, please specify;_____ Stop (if applicable): ___/___/___

Study number: ☐

Date of inclusion: ___/___/___

DISCHARGE INTERVENTION CENTER CRF

Interventions and diagnoses during hospital stay—intervention center

Atrial fibrillation de novo:	o No	o Yes
Aneurysma spurium:	o No	o Yes
Treatment for aneurysma spurium:	o No treatment o (Pro) thrombin injection o Compression bandage	o Surgical intervention o Other, _____
Groin hematoma:	o No	o Yes
Intubation (excl. intubation for EVT):	o No	o Yes
Hemicraniectomy:	o No	o Yes
External ventricular drain (EVD):	o No	o Yes
Major medical/surgical intervention:	o No If yes, please specify;_____	o Yes

Admissions—intervention center

Patient admitted to the ICU:	o No	o Yes, total days: _____
Patient admitted to Medium Care:	o No	o Yes, total days:_____
Patient admitted to Stroke Unit:	o No	o Yes, total days: _____
Patient admitted to General Ward:	o No	o Yes, total days:_____

Discharge—intervention center

Was the patient discharged (or did the patient die during admission):	o No	o Yes
Discharge destination:	o Patient died o Home o Geriatric rehabilitation o Nursing home long stay	o Rehabilitation center o Other hospital (complete discharge second hospital) o Other, _____
Date of discharge or death:	___/___/____	

(S)AE Check

Did the patient experience one of more (serious) adverse events:	o No	o Yes **If yes, please complete (S)AE form(s) in Castor and report to sponsor!**

Review all Data for this Visit

Physician Date: ___/___/___ Signature: _____	Study Nurse Date: ___/___/___ Signature: _____

Other, comments:_____

_____

_____

_____

Study number: ____ Date of inclusion: ___/___/___

Discharge Form

Please fill this form in via the CASES website, https://cases-trial.eu/ontslaggegevens-discharge-data.html, NOT in CASTOR!

Patient

Center: _____ Study ID: _____

First name + surname: _____

Street +house number: _____

Zipcode: _____ Town/City: _____

Telephone number(s): _____ Email address: _____

In which language should the patient be addressed:
- o Dutch
- o English
- o French

General Practitioner

First name + surname: _____

Town/City: _____ Telephone number: _____

Discharge destination

Discharge destination:
- o Home
- o Rehabilitation facility
- o Nursing home
- o Hospital
- o Other

Name of discharge destination: _____

Does the patient want to share contact details of other relatives/acquaintances?
- o No
- o Yes

Which person should be contacted first:
- o Patient
- o Contact person 1
- o Contact person 2

Contact person 1
Name + surname: _____
Relation the patient: _____
Telephone number(s): _____
Email address: _____

Contact person 2
Name + surname: _____
Relation the patient: _____
Telephone number(s): _____
Email address: _____

Review all Data for this Visit

Physician
Date: ___/___/___
Signature: _____

Study Nurse
Date: ___/___/___
Signature: _____

Other, comments: _____

Study number: _____ Date of inclusion: ___/___/___

DISCHARGE SECOND HOSPITAL CRF

Neuroimaging—second hospital

Any additional neuroimaging performed during hospital stay (excl. study imaging):	○ No	○ Yes Send all neuroimaging performed during admission to the study team.

Medication during hospital stay—Intervention center

Antiplatelet agents:	○ No	○ Yes
Acetylsalicylic acid/carbasalate calcium:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Clopidogrel:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Dipyridamole:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Ticagrelor:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Other:	○ No Start: ___/___/___	○ Yes If yes, please specify;_____ Stop (if applicable): ___/___/___
Direct Oral Anticoagulants:	○ No	○ Yes
Apixaban (Eliquis):	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Dabigatran (Pradaxa):	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Edoxaban (Lixiana):	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Rivaroxaban (Xarelto):	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Other, _____	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Vitamin K antagonist:	○ No	○ Yes
Acenocoumarol:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Phenprocoumon:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Heparin:	○ No	○ Yes
Prophylactic heparin:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Therapeutic heparin:	○ No Start: ___/___/___	○ Yes Stop (if applicable): ___/___/___
Other anticoagulants:	○ No Start: ___/___/___	○ Yes If yes, please specify;_____ Stop (if applicable): ___/___/___

Study number: ____ Date of inclusion: ___/___/___

DISCHARGE SECOND HOSPITAL CRF

Interventions and diagnoses during hospital stay—second hospital

Atrial fibrillation de novo:	o No	o Yes
Aneurysma spurium:	o No	o Yes
Treatment for aneurysma spurium:	o No treatment o (Pro) thrombin injection o Compression bandage	o Surgical intervention o Other, _____
Groin hematoma:	o No	o Yes
Intubation (excl. intubation for EVT):	o No	o Yes
Hemicraniectomy:	o No	o Yes
External ventricular drain (EVD):	o No	o Yes
Major medical/surgical intervention:	o No If yes, please specify;_____	o Yes

Admissions—second hospital

Patient admitted to the ICU:	o No	o Yes, total days: _____
Patient admitted to Medium Care:	o No	o Yes, total days:_____
Patient admitted to Stroke Unit:	o No	o Yes, total days: _____
Patient admitted to General Ward:	o No	o Yes, total days:_____

Discharge—second hospital

Was the patient discharged (or did the patient die during admission):	o No	o Yes
Discharge destination:	o Patient died o Home o Geriatric rehabilitation o Nursing home long stay	o Rehabilitation center o Other hospital o Other, _____
Date of discharge or death:	___/___/____	

(S)AE Check

Did the patient experience one of more (serious) adverse events:	o No	o Yes **If yes, please complete (S)AE form(s) in Castor and report to sponsor!**

Review all Data for this Visit

Physician
Date: ___/___/___
Signature: _____

Study Nurse
Date: ___/___/___
Signature: _____

Other, comments:_____
_____
_____
_____

Study number: _____ Date of inclusion: ___/___/___

90 day follow-up CRF

Date & Time of follow-up assessment: ___/___/____ ___:___	
Residence of the patient at 90 days after index event:	o Home o Rehabilitation facility o Acute care hospital o Nursing home o Other, please specify: _____
What is the suspected etiology of the index stroke:	o Large artery atherosclerosis o Small-vessel occlusion (lacune) o Cardio-embolism o Stroke of other determined etiology o Stroke of undetermined etiology
If stroke of undetermined etiology:	o Two or more causes identified o Negative evaluation o Incomplete evaluation
Did any of the following events occur:	o Recurrent ipsilateral TIA/amaurosis fugax o Recurrent ipsilateral ischemic stroke o Any stroke/TIA o Any intracranial hemorrhage o Any extracranial hemorrhage o Death o No event occurred **Please complete (S)AE form(s) in Castor and report to sponsor!**

Medication (at home)

Antiplatelet agents:	o No	o Yes
Acetylsalicylic acid/carbasalate calcium:	o No	o Yes
Clopidogrel:	o No	o Yes
Dipyridamole:	o No	o Yes
Ticagrelor:	o No	o Yes
Other:	o No	o Yes If yes, please specify;_____
Vitamin K antagonist:	o No	o Yes
Acenocoumarol:	o No	o Yes
Phenprocoumon (Marcoumar):	o No	o Yes
Direct Oral Anticoagulants:	o No	o Yes
Rivaroxaban (Xarelto):	o No	o Yes
Dabigatran (Pradaxa):	o No	o Yes
Apixaban (Eliquis):	o No	o Yes
Edoxaban (Lixiana):	o No	o Yes
Other:	o No	o Yes If yes, please specify;_____
Therapeutic heparin:	o No	o Yes
Lipid lowering therapy:	o No	o Yes
High intensity statin:	o No	o Yes
Low intensity statin:	o No	o Yes
Ezetimibe:	o No	o Yes
Fibrate:	o No	o Yes
PCSK9-inhibitor:	o No	o Yes
Other:	o No	o Yes If yes, please specify;_____

ⓘ High-intensity statin; Atorvastatin 40-80mg daily or rosuvastatin 20-40mg daily

Low/moderate intensity statin: Atorvastitin 10-20mg daily, rosuvastatin 5-10mg daily, simvastatin 10-40mg daily, pravastatin 10-90mg daily, Lovastatin 20-40mg daily, Fluvastatin 20-80mg daily, Pitavastatin 1-4mg daily

Study number: _____ Date of inclusion: ___/___/___

90 day follow-up CRF

Antihypertensive drugs:	o No	o Yes
ACE-inhibitor:	o No	o Yes
Angiotensin II receptor blocker:	o No	o Yes
Beta blocker:	o No	o Yes
Calcium channel blocker:	o No	o Yes
Diuretic:	o No	o Yes
Other:	o No	o Yes
		If yes, please specify;_____
Anti-diabetic medication:	o No	o Yes
Insulin:	o No	o Yes
Oral antidiabetic agents:	o No	o Yes
Other:	o No	o Yes
		If yes, please specify;_____

(S)AE Check

Did the patient experience 1 or more (serious) adverse events between discharge and 90 day follow up:	o No	o Yes **If yes, please complete (S)AE form(s) in Castor and report to sponsor!**

Carotid ultrasound

Was a carotid ultrasound performed 90 days after the index event:	o No	o Yes
Date & Time of carotid ultrasound: ___/___/____ ___:___		
Part of routine care:	o No	o Yes
Symptomatic carotid artery occluded on ultrasound:	o No	o Yes
Left carotid artery:		
Grading of **left** carotid artery stenosis on duplex ultrasound:	o 0-49% o 50-69% o 70-89%	o >90% o Near-occlusion o Occlusion

Peak systolic flow velocity in the left common carotid artery: _____cm/s
Peak systolic flow velocity in the proximal left internal carotid artery: _____cm/s
End diastolic flow velocity in the proximal left internal carotid artery: _____cm/s
Peak systolic flow velocity in the distal left internal carotid artery: _____cm/s
End diastolic flow velocity in the distal left internal carotid artery: _____cm/s

Right carotid artery:		
Grading of **right** carotid artery stenosis on duplex ultrasound:	o 0-49% o 50-69% o 70-89%	o >90% o Near-occlusion o Occlusion

Peak systolic flow velocity in the right common carotid artery: _____cm/s
Peak systolic flow velocity in the proximal right internal carotid artery: _____cm/s
End diastolic flow velocity in the proximal right internal carotid artery: _____cm/s
Peak systolic flow velocity in the distal right internal carotid artery: _____cm/s
End diastolic flow velocity in the distal right internal carotid artery: _____cm/s

Review all Data for this Visit

Physician
Date: ___/___/___
Signature: _____

Study Nurse
Date: ___/___/___
Signature: _____

Other, comments:_____
_____
_____
_____

Study number: _____

Date of inclusion: ___/___/___

(SERIOUS) ADVERSE EVENTS ((S)AE) CRF

(S)AE number: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10

General information

Initials investigator:_____ Signature investigator:

Date of report: ___/___/___ Date of (S)AE onset ___/___/___

Description of (S)AE (in Dutch or English):

_____

_____

_____

_____

_____

_____

Deterioration and neuro-imaging

Neurologic deterioration of 4 points or more on NIHSS:	o Yes	o No
Neurologic deterioration of 2 points or more on 1 NIHSS subcategory:	o Yes	o No
Was there neuro-imaging performed for this (S)AE:	o Yes	o No
Was this event an adverse event or a serious adverse event:	o AE (continue to relationship with study procedures)	o SAE

Serious Adverse Event category, please choose one:

o Results in death
o Life threatening (at the time of event)
o Requires prolonged hospitalization
o Results in persistent or significant disability or incapacity
o Other, please specify: _____
o Not listed above (i.e. not a **serious** adverse event)

SAE expected?

An SAE is 'expected' if this is one of the known side effects of the study treatment or one of the common (potentially) serious complications after stroke.

o No o Yes

Select most likely cause of SAE, please choose one:

o Stroke progression
o New ischemic stroke, which territory_____
o Intracranial hemorrhage
o Extracranial hemorrhage
o Cardiac Ischemia
o Allergic reaction
o Pneumonia
o Other infection, _____
o Other, _____

Was there another cause for SAE, you may choose multiple

o No o Yes
o Stroke progression
o New ischemic stroke
o Intracranial hemorrhage
o Extracranial hemorrhage
o Cardiac Ischemia
o Allergic reaction
o Pneumonia
o Other infection, _____
o Other, _____

Relationship with the study procedures:

o None
o Unlikely
o Possible
o Probable
o Definite

Actions regarding study participation

o None
o Interrupted
o Stopped
o Other, please specify: _____

Outcome

o Resolved without sequelae date: ___/___/___
o Resolved with sequela(e) date: ___/___/___ and describe sequela(e): _____
_____
o Ongoing (pending)
o Death date: ___/___/___

Study number: ____

Date of inclusion: ____/____/____

(SERIOUS) ADVERSE EVENTS ((S)AE) CRF

Review all Data for this Visit

Physician
Date: ___/___/___
Signature: _____

Study Nurse
Date: ___/___/___
Signature: _____

Other, comments:_____
_____
_____
_____