

Study number:

Date of inclusion: __/__/__

Subject: CASES

Dear colleague/co-investigator,

A new patient in your hospital has been included in the CASES trial. Enclosed you will find a checklist as a reminder of the study activities for the next days.

The paper Case Report Forms (CRF's found on the website) are a resource. You must fill in the data collected in the electronic CRF (eCRF) using Castor EDC. The first business day after randomization, the patient's Castor EDC record will be activated.

Day 0 (date of inclusion)

- Indicate in the patient's medical record that the patient is included in the CASES trial and mention the study number and center ID.
- NIHSS-score, to be taken by a physician.
- Imaging: if baseline NCCT/CTA/CTP were performed at a referring center, please request the imaging data and add these data to the medical record.
- Complete the following paper worksheets:
 - o Baseline (event characteristics, history...)
 - o Endovascular treatment
 - o Study treatment (depending on randomization arm)
- Schedule a NCCT and CTA at 24h (+- 12h) after randomization.
- If SAE: send a notification mail to cases-trial@umcg.nl with the subject 'SAE – study number' (and complete eCRF directly via Castor EDC).

Day 1 (24h after randomization – always at the EVT center)

- Obtain the deferred informed consent, preferably within 24h. Check the level of consent and collect data accordingly. Also see the SOP 'patient information and deferred consent (CASES)' via [CASES - trial protocol and trial documents](#).
- Follow-up NCCT and CTA at 24h (+-12h) after randomization.
- NIHSS-score at 24h, to be taken by a physician.
- Complete the following paper worksheets:
 - o Clinical follow-up: 24 hour follow up & 24 hour imaging
- When informed consent has been obtained, you can start entering data in the eCRF via Castor EDC
 - o Informed consent
 - o Baseline (event characteristics, history...)
 - o Endovascular treatment
 - o Study treatment (depending on randomization arm)
 - o Clinical follow-up: 24 hour follow up & 24 hour imaging
- If SAE: complete eCRF directly via Castor EDC and send a notification mail to cases-trial@umcg.nl with the subject 'SAE – study number'.

Study number:

Date of inclusion: __/__/__

Day 5-7 after randomization (or earlier upon discharge)

- NIHSS-score to be taken by a physician.
 - o In case of transfer to referring hospital before day 6 +- 1 day, NIHSS score at discharge should be provided by the referring hospital.
- Complete the following paper worksheets and enter data in the eCRF via Castor EDC:
 - o Clinical follow-up: day 6 +- 1 day follow-up
- If SAE: complete eCRF directly via Castor EDC and send a notification mail to cases-trial@umcg.nl with the subject 'SAE – study number'.

Patient is discharged:

- Go to [Ontslaggegevens / Discharge data \(cases-trial.eu\)](#). There, fill in additional information about the patient (discharge form). This information will be encrypted and send securely and is needed for the telephone follow-up.
- Schedule a duplex ultrasound of the carotid artery, 90 days after the index event. Give the letter about the follow-up appointment (duplex ultrasound of the carotid artery) to the patient, with an additional copy to at least one contact person.
- Complete the following paper worksheets and enter data in the eCRF via Castor EDC:
 - o Clinical follow-up: Discharge – intervention center
 - o Deferred treatment (depending on randomization arm)
- Transfer the pseudonymized imaging data (baseline NCCT/CTA/CTP, DSA and follow-up NCCT/CTA) mentioning the study number.

In case of transfer to (referring) hospital:

- Inform the referring hospital that the patient is participating in this trial.
- In case of transfer before day 6 +- 1 day, NIHSS score at discharge should be provided by the referring hospital.
- Complete the following paper worksheets and enter data in the eCRF via Castor EDC:
 - o Clinical follow-up: Discharge – second hospital (transfer)

Day 90 after randomization:

- Duplex ultrasound of the carotid artery
- Complete the following paper worksheets and enter data in the eCRF via Castor EDC:
 - o Deferred treatment (if applicable)
 - o Follow-up 3 months (unblinded)
- If SAE: complete eCRF directly via Castor EDC and send a notification mail to cases-trial@umcg.nl with the subject 'SAE – study number'.

If there are any questions or ambiguities, please feel free to contact the CASES study team.

Kind regards,

The CASES team

Louise Maes, Dora van Elk, Maarten Uyttenboogaart, Robin Lemmens and Paul Nederkoorn
Coordinating investigators CASES

E: cases-trial@umcg.nl

T: +31 6 5272 4593