Newsletter #4 - April 2024

Dear Investigators,

Time for a CASES update! Currently, 27 out of 28 participating centers have been initiated. Inclusion progress is going exceptionally well. Notably, 21 centers have already enrolled at least one patient, resulting in a total of 160 patients included thus far.

In January, our first steering committee meeting was organized. Some cases were presented, including one on pseudo-occlusion and one with a severe bleeding complication, which led to an interesting discussion.

Our first DSMB safety analysis also took place on the 1st of March. Based on the review and discussion of the provided safety data, the DSMB recommends continuing the trial as planned.

Over the past months, the CASES team has organized several carotid artery stenting training sessions with simulators provided by Terumo, receiving positive feedback and engagement from participants. Building on this success, an additional training session will be organized in Brussels.

Furthermore, the team was asked to write a brief literature overview on the treatment of the carotid lesion in patients with a tandem lesion and acute ischemic stroke. This effort resulted in a notable publication in the European Journal of Vascular and Endovascular Surgery (EJVES) Vascular Forum, entitled “Immediate Carotid Artery Stenting or Deferred Treatment in Patients With Tandem Carotid Lesions Treated Endovascularly for Acute Ischaemic Stroke” (https://pubmed.ncbi.nlm.nih.gov/38234597/).

For the upcoming months we have set some new goals: organizing a second steering committee at the European Stroke Organisation Conference (ESOC) in Basel, publishing the CASES trial protocol and reaching the milestone of 200 patients by the end of June!

With optimism and immense gratitude for everyone’s dedication and efforts, we look forward to the coming months and hopefully even more inclusions!

The CASES coordinating team
Louise, Anne, Annemie, Nynke, Robin, Paul, Maarten and Dora

Symptomatic intracranial hemorrhage

The CASES trial uses the Heidelberg criteria for the definition of symptomatic intracranial hemorrhage (sICH). Please keep in mind that hemorrhagic transformation is very common among patient treated with EVT but this is not necessarily a sICH.

When reporting a hemorrhage as an (S)AE make sure to differentiate between sICH and hemorrhagic transformation.
Please report a sICH when there is an increase in the NIHSS score of 4 or more points or an increase in the score for an NIHSS subcategory of 2 or more points ascompared with baseline or the lowest value before deterioration, with the presence of parenchymal hemorrhage type 2. Parenchymal hemorrhage type 2 is defined as an intracranial hemorrhage that involves more than 30% of the infarcted area with a substantial space-occupying effect or that is remote from the original infarcted area.

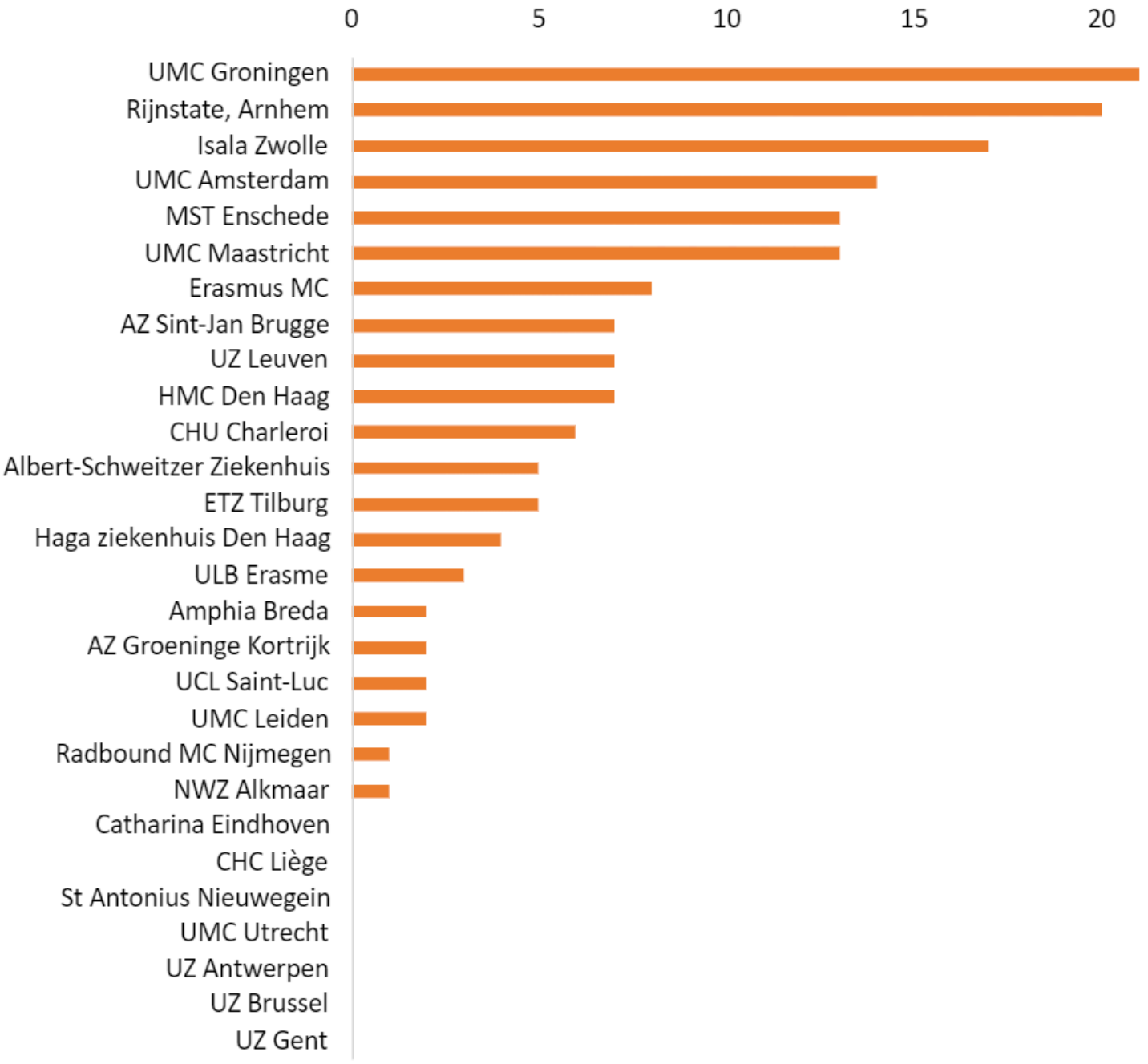
Discharge form

Please remember to fill in the discharge form via the website: https://cases-trial.eu/CASES/ontslag.php

Please inform us in case of:

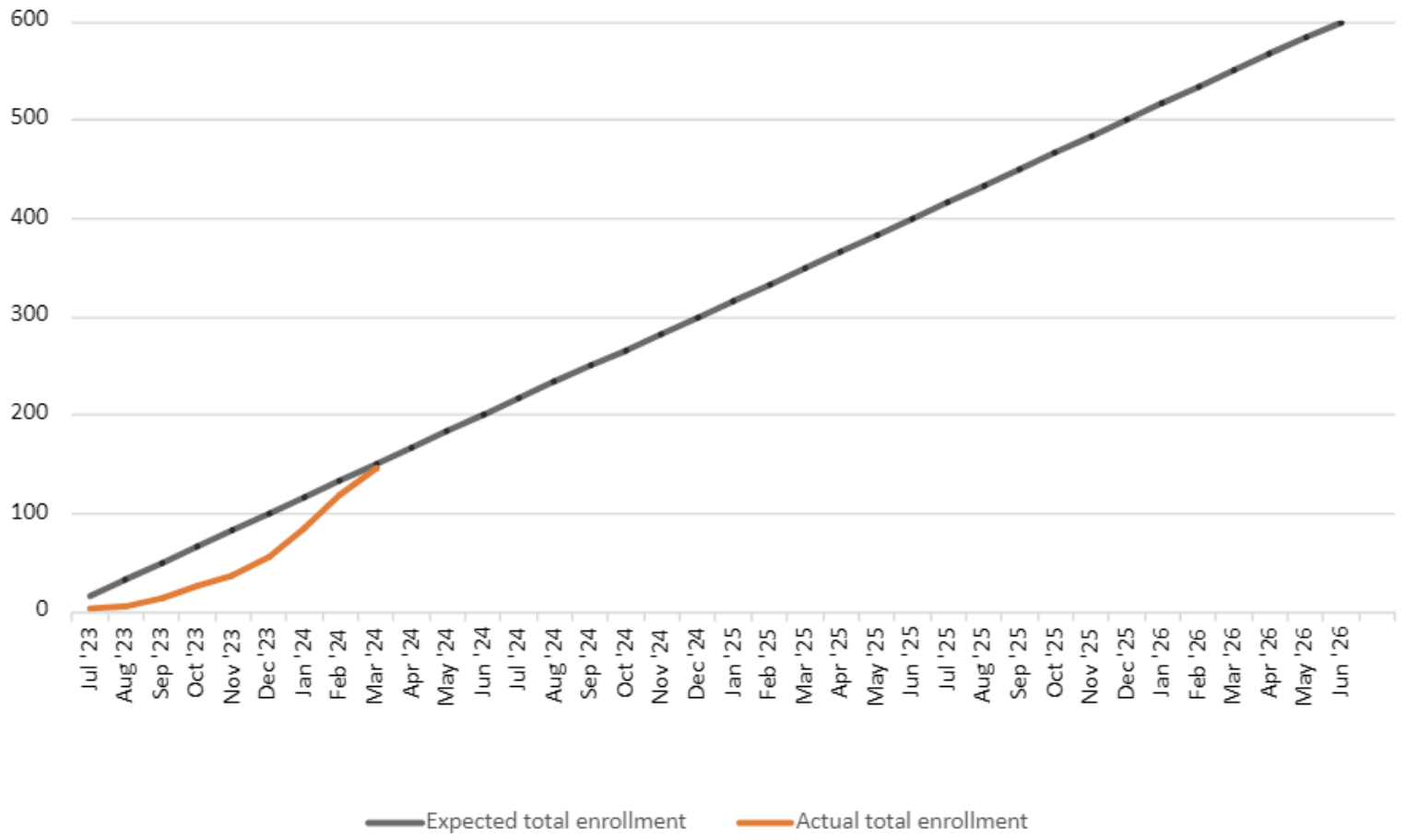
- SAE's
- Crossover (with and without valid reason)
- Non-compliance with inclusion/exclusion criteria
- Failing to obtain or withdrawal of informed consent
- Protocol deviations regarding used stents/EVT devices, imaging not done in time window

For items listed above and any questions please contact us at: cases-trial@umcg.nl
or via telephone +31 6 5272 4593



Let them eat cake!

Centers receive cake when they've included 10 patients!
So far, UMC Groningen, Isala, Medisch Spectrum Twente, Rijnstate, Maastricht UMC and AMC have celebrated this milestone.



ESOC meeting

ESOC 2024 is taking place in Basel this year!
On the 15th of May from 16:00-17:00 the CASES ESOC meeting has been planned, Studio 5 in the Marriot Hotel.
Please join us to discuss the progress of the CASES trial as well as interesting cases and any issues you have encountered.

Afterwards, we can visit the Nederlandse Beroerte Borrel together at the Auld Dubliner!

The Belgian Stroke drinks is on Thursday evening at the Baltazar Bar!

Carotid artery stenting training session 2

On the 30th of January the second catorid artery stenting training took place!
Interventional radiologists from multiple centers were able to practice stenting with simulators and vessel models provided by Terumo.

FAQ

Q: Do we have to perform the **CTA** if the patient has a severely **decreased kidney function**?

A: This is a pragmatic trial and the safety of the patient is the most important. In case of an estimated eGFR <30 mL/min/1.73m2 it is okay to skip the CTA. However, we would like you to perform the NCCT.

Q: Does the **carotid ultrasound at 3 months** have to be performed at the intervention center?

A: The carotid ultrasound should be performed at the intervention centre, as payment (if the carotid echo is performed as part of research and not part of routine care!) is made to the intervention center based on visits such as the carotid ultrasound. We will not be able to pay the referring center for the carotid ultrasound.

Q: How do we complete the **eCRF when a patient has died**?

A: If a patient dies, the upcoming visits may be reported as missing data. You do this by clicking on the 'wheel' to the right of a question, form or even entire visit and selecting the 'user missing' option. In this way it is clear for the sponsor that follow-up was completed for this patient.

Q: Should we **report asymptomatic intracranial hemorrhages or EVT complications** as AE's?

A: Yes, you can do this by adding an (S)AE report in Castor.

Q: I've filled in all visits in **CASTOR**, however the **progress** bar does not show 100% for data collection?

A: In CASTOR there are a few hidden visits such as blinded follow up and imaging core lab. These forms are not visible but do participate in the progress.

Documents such as the study protocol, information letters/informed consent forms and paper CRF worksheets can be found on the CASES website: www.cases-trial.eu/
If you have any questions don't hesitate to contact us via cases-trial@umcg.nl or +31 6 5272 4593.

The CASES study team

Paul Nederkoorn
Principal Investigator

Maarten Uyttenboogaart
Principal Investigator

Robin Lemmens
Principal Investigator

Theodora van Elk
Trial Coordinator

Louise Maes
Trial Coordinator

Nynke Nicolaij
Research Nurse

Anne van der Meij
Fellow Neurology

Annemie Devroye
Research Nurse

E-mail	Phone number	Website
cases-trial@umcg.nl	+31 6 5272 4593	www.cases-trial.eu/