Newsletter - July 2024

Dear investigators,

One year of CASES!

On July 5th, 2023, the very first patient was included in the CASES trial by UMC Groningen. Approximately one year later, we have included 241 patients, which is incredible!

We have seen a (hopefully vacation related) dip in inclusion. We strongly encourage you to include all eligible patients so that we can maintain the momentum during the summer and reach our next goal: our first efficacy interim analysis by the end of the year when 300 patients reach their 90-day follow-up.

On the 19th of July the second DSMB meeting is planned. We will update you shortly.

In May, we organized our second steering committee meeting at ESOC in Basel, which was a great succes. Some interesting discussions regarding the inclusion of patients with low ASPECTS led to the conclusion to not include these patients (see below).

For the upcoming months, we have set some new goals: a Belgian carotid artery stent training will take place on September 9th, in Groot-Bijgaarden. Feel free to subscribe if you would like to join. We also plan to publish our trial protocol paper before the end of the year.

We are very thankful for all your efforts and look forward to the next few months!

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

ESOC 2024

During ESOC we organized our second steering committee meeting. There was interesting discussion and it was good to see everyone in Basel!

We also presented a poster regarding the progress of the CASES trial!

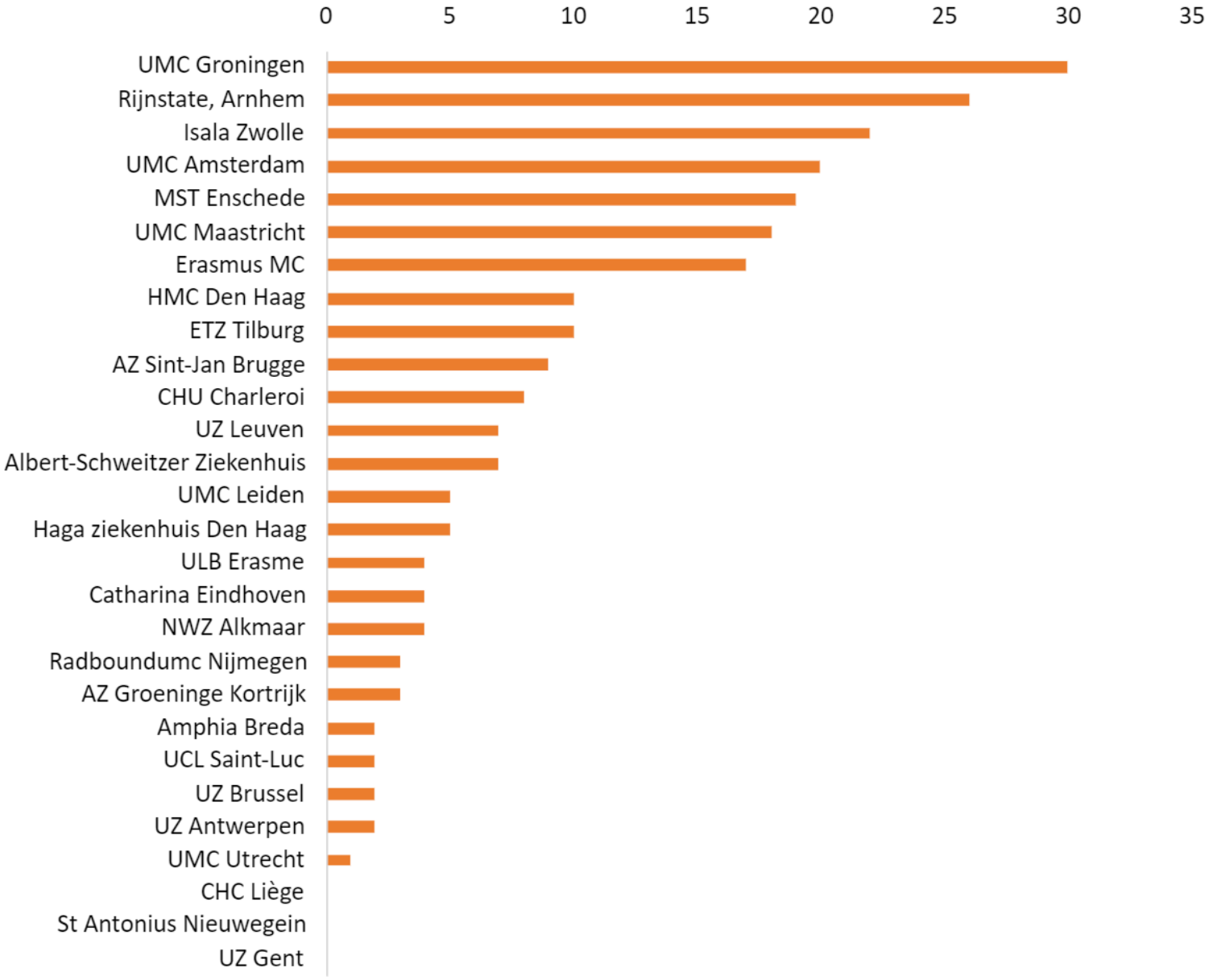
Link to ESOC 2024 poster

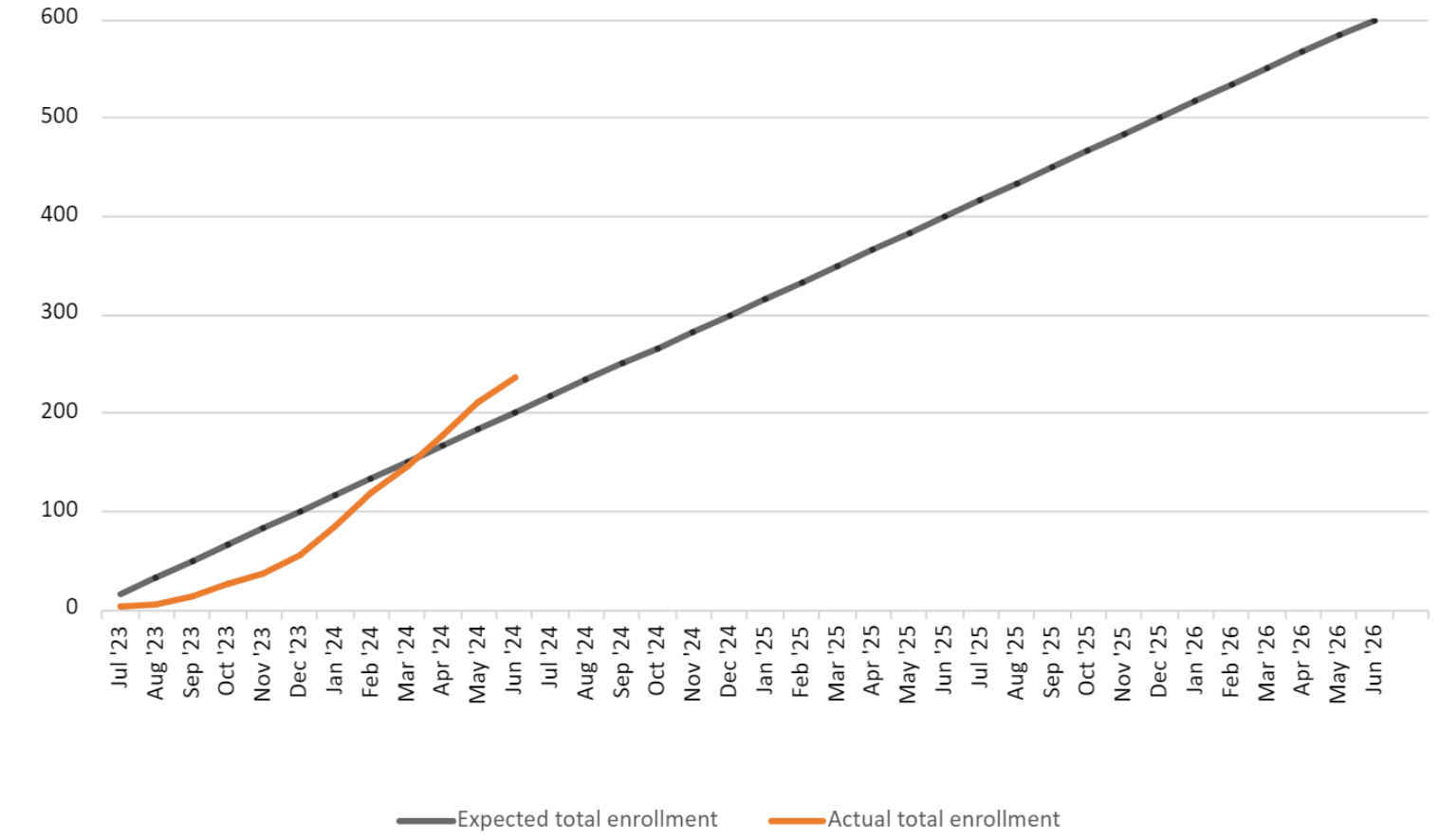
Exclusion of patients with low ASPECT score

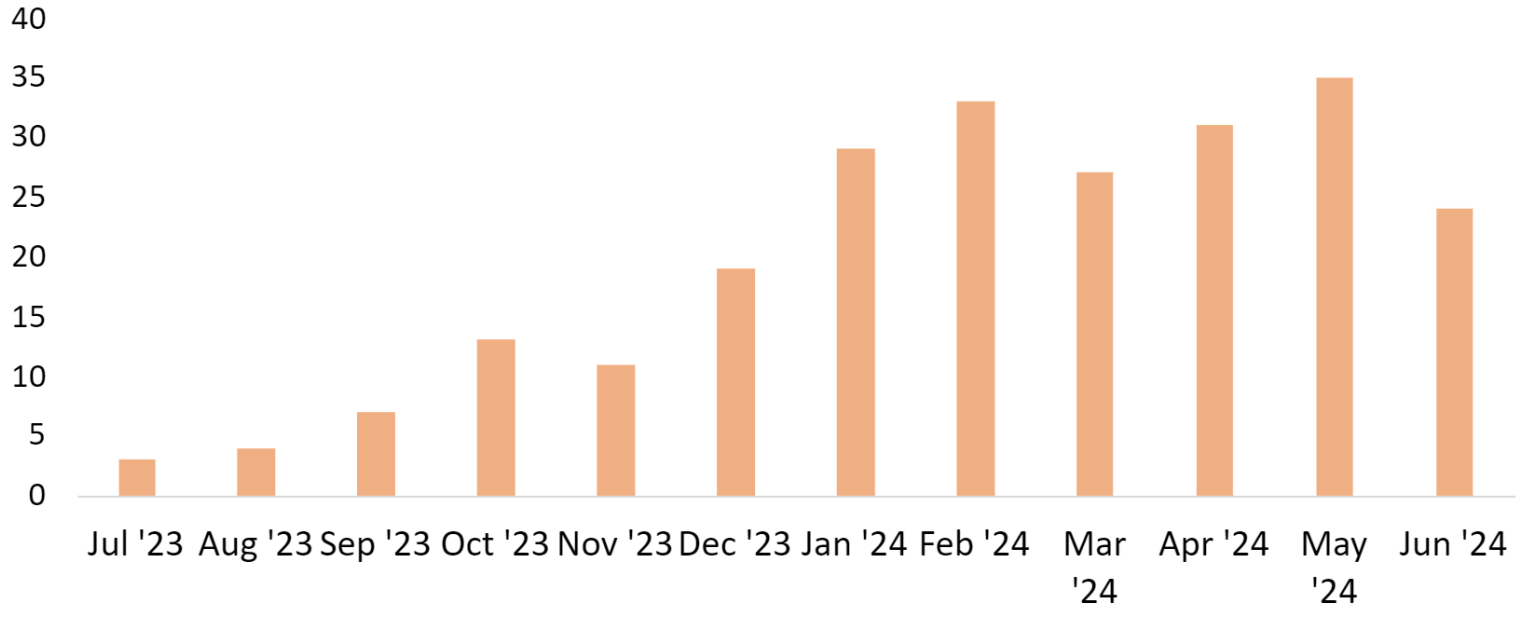
Recently, 5 trials have been published about the efficacy of EVT among patients with low ASPECT score (ASPECT score <6). Although all these trials found a treatment benefit of EVT, the chance of favorable outcome at 90 days was low (mRS score 0-2 ranging between 13%-30% in the EVT arm). This would imply that for these patients in the deferred treatment group, only a few would be eligible for CEA or CAS. In addition there are some concerns that the risk of intracranial hemorrhage may be increased in this subgroup. Our colleague trialists from EASI-TOC, TITAN and PICASSO trials are excluding these patients as well. Therefore the steering committee decided to change the CASES protocol and exclude patients with ASPECTS < 6. We will send the new protocol to you once the METc has approved the amendements. In the

meantime, we would like to ask you to already communicate this message in your center to all the persons who include patients.

CASES inclusion 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.

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

Frequently Asked Questions

Q: What if a patient is discharged to the referring center before the 5-7 days follow-up visit?

A: In case of transfer, the referring hospital is requested to provide the NIHSS score at 5-7 days (or discharge). Ask the referral center to provide the patient's discharge letter and any information regarding the deferred treatment (if applicable) to complete tthe visits 'discharge second hospital transfer, part 1 & 2', and 'deferred treatment'. The 90-day duplex ultrasound should be planned in the intervention center. Information to complete the '90-day follow up (unblinded)' visit can be requested from the referral center.

Q: What if the interventional radiologist used a device that is not approved according to trial protocol?

A: This is considered a 'minor deviation'. Please complete a deviation form and report it tto the sponsor. We plan to add some devices, such as the Aperio Hybrid stent retriever, in our next protocol amendment.

Q: How do we have to follow-up on (S)AE's?

A: As long as an AE or SAE is ongoing, you must continue to follow-up until the patient has reached the 90 day follow up (+-14 days). You can update (S)AE's in Castor and complete a new paper form (as source) when additional information is available.

Other Frequently Asked Questions can be found on our website: https://cases-trial.eu/faq.html

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
cases-trial@umcg.nl

Phone number
+31 6 5272 4593

Website
www.cases-trial.eu/