Newsletter - October 2024

Dear investigators,

The 300th patient has been included!

Thank you all for your continued efforts in the CASES trial. We are delighted with the progress so far and hope to continue with the fast inclusion rate.

Discharge form

The clinical endpoint is evaluated by centralized follow-up and therefore it is of great importance to fill in the discharge form (via the CASES website: https://cases-trial.eu/CASES/ontslag.php). It is crucial that the contact details, including phone number of the patient or legal representative are provided. We strongly recommend that these details are obtained through an active conversation with the patient or their legal representative during hospitalization. Without this information, we will be unable to contact the patient for the primary endpoint. Please ensure that both the patient's and/or legal representative's contact details are filled in accurately and verified. Thank you for your cooperation and attention to this important process.

Data Safety and Monitoring Board (DSMB)

The DSMB met again on the 30th of August to review the trial progress and the additionally provided trial data. Based on the review and discussion of the provided safety data, the DSMB recommends continuing the trial as planned. As we have now included 300 patients the preplanned interim efficacy analysis is approaching as this will be after 300 patients have reached the primary endpoint.

Protocol amendment

We are currently finalizing the trial protocol paper and hope to submit this paper before the end of the year. In addition, we will submit the protocol amendment to the ethical boards soon.

New PhD in CASES team

A third PhD will be appointed in the Amsterdam University Medical Center and will join the CASES team later this year. The topic will be long-term follow-up of patients included in CASES and this project will be carried out together with the rehabilitation work-package in CONTRAST.

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

Deferred Informed Consent

Informed Consent Reminder for Investigators and Study Coordinators

We would like to remind all investigators and study coordinators of the following important procedure:

When initial deferred consent has been obtained from a participant's legal representative, it is crucial to also seek consent from the participant directly once their mental competence is restored. This may be at various stages of recovery, such as a few days before discharge, during rehabilitation, or at the 90-day follow-up consultation. If obtaining consent from the participant is not possible (e.g. poor functional recovery, loss-to-follow-up), it is essential to document this on the informed consent log.

For investigators in Belgium, you may continue using the existing "Information and Consent Form Participant/Legal Representative," with the participant now adding their signature.
For those in the Netherlands, please use the "Informatiebrief en toestemmingsformulier tweede instantie" to fulfill this requirement.

For more information regarding deferred informed consent and some helpful tips please visit:
https://cases-trial.eu/DOC/SOP%20patient%20information%20and%20deferred%20consent%20(CASES).pdf

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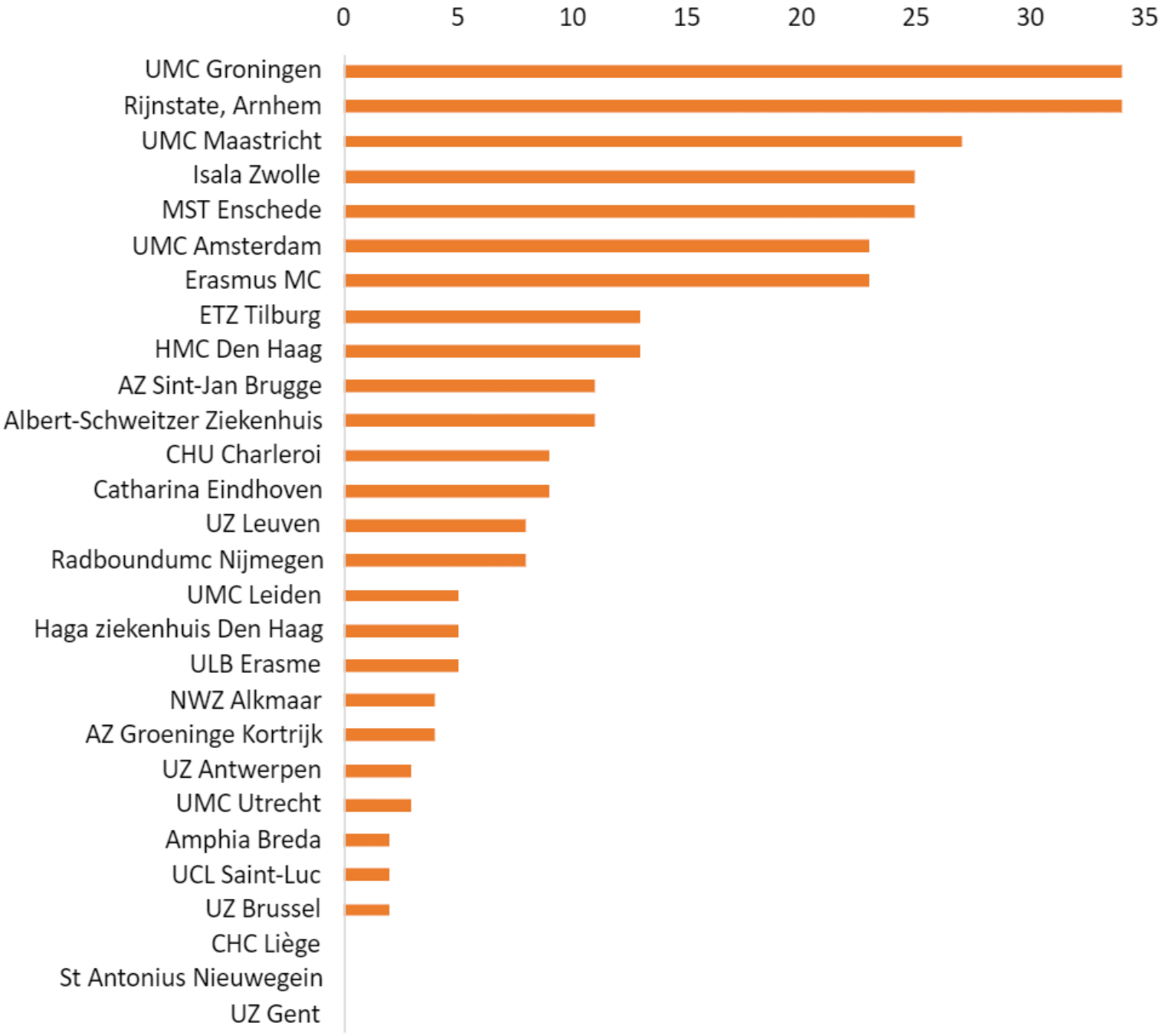
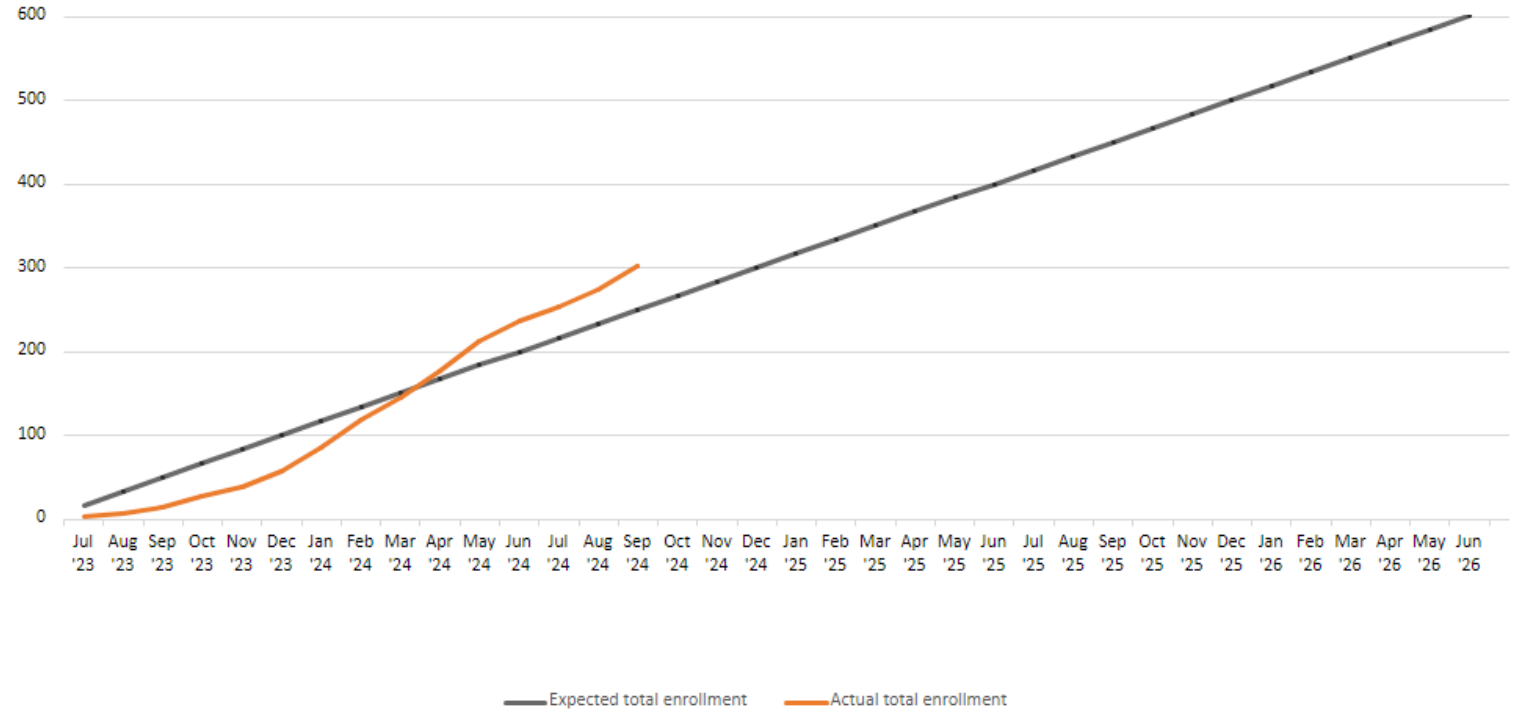
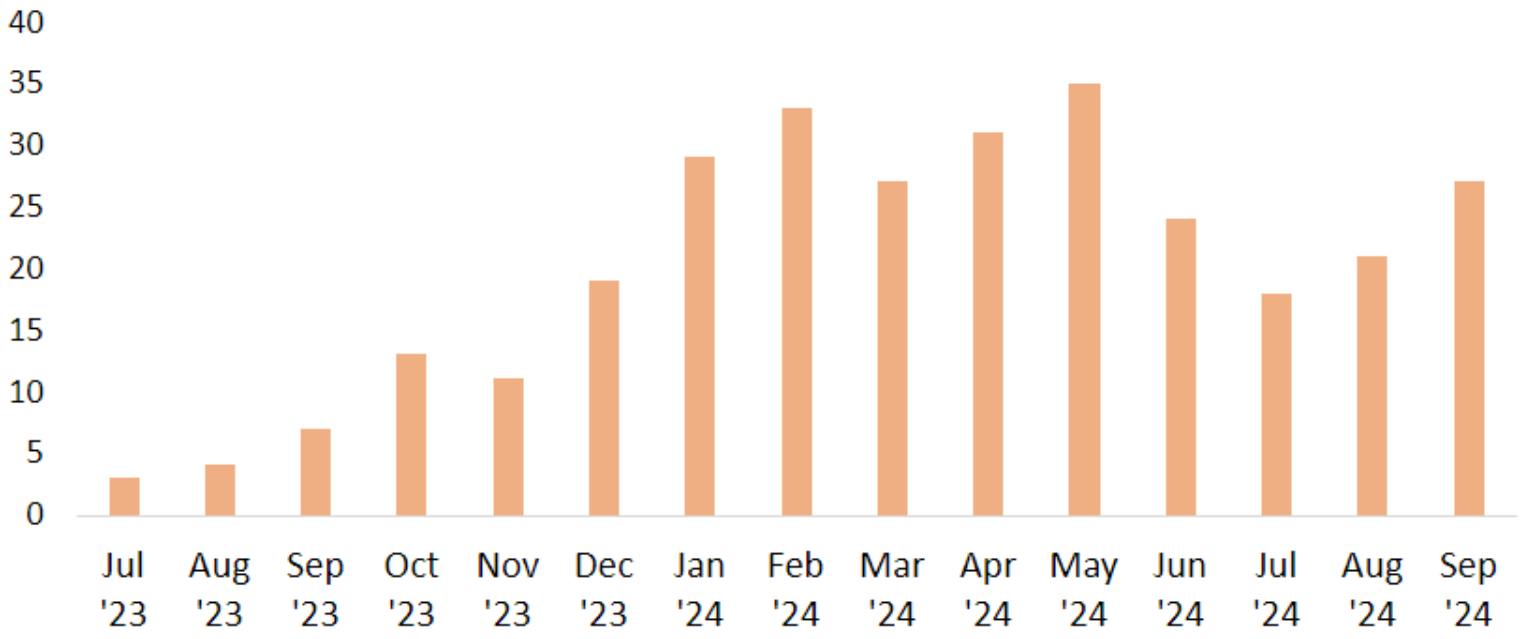
Recently, AZ Sint Jan included their 10th patient and received cake to celebrate!

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 the 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 to 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

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