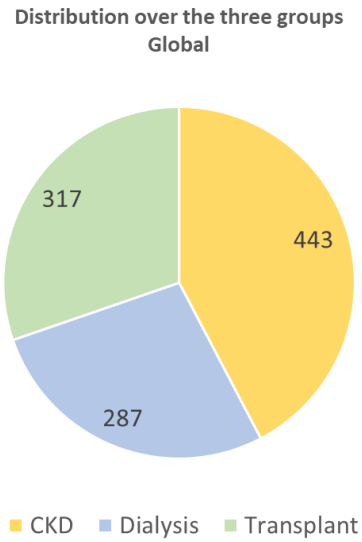
Newsletter

Issue 13· Sept 2024

Recruitment and study progress

We hope you all had a great (summer) holiday! During the summer inclusion has been steadily going on and at this moment **more than 1000** participants were screened. Great job! To specify, a total of 1055 patients were screened and 964 patients were randomized.

The diagram below shows the inclusion per subgroup. The CKD group is still the largest subgroup with 443 participants at this moment. The aim is to include 400-600 participants for each subgroup and this means that the subgroup of CKD patients is expected to close in the coming months. However, we would like to emphasize the dialysis group that still needs attention.



REDCap topic of the month

Temporary and definitive stop study medication

Within REDCap there is a dedicated Case Report Form (CRF) for documentation of a temporary stop study medication and a dedicated CRF for documentation of a definitive stop study medication. Please select the correct version when a participant (temporarily) stops study medication.

Protocol version 10

We would like to inform you about the new protocol version 10 that has recently been approved. This new version has been sent via e-mail and an overview of the changes can be found on page 4 of the protocol.

SAE reporting newsletter July 2024

We would like to clarify a few items regarding SAE reporting that were part of the newsletter in July 2024.

- Multiple events during hospitalization

The aim of the last newsletter was to ensure that the outcome of a hospitalization is not reported as a separate SAE. E.g. admitted to the hospital, however, admission resulted in death. This should be reported as one SAE. If several events happen, the second event may have resulted in prolongation of the hospitalization and hence should be reported separately. For example, a patient is admitted to the hospital for a gastrointestinal bleeding. During the hospitalization the patient develops a pneumonia. As the latter may have resulted in prolongation of the hospitalization this should be reported as a separate SAE.

- Completeness SAE forms

Please ensure that the SAE form is as complete as possible before sending to the SAE event team.

- Blinding discharge letter

Please ensure that discharge letters are blinded properly and hence do not contain personal information from the participant. To blind the discharge letter you can either use the Acrobat pro option 'redacting' or you can black tape the paper form and make a scan of this.

When in doubt—please reach out the Sponsor team to consult on how to report an SAE.

Fantastic news!

As inclusion is going well there are only +/- 500 screenings more to go, to reach the major milestone of 1500 participants. Thank you all for your great contribution! Moreover, Belgium will start in the coming months with including patients. Professor Dirk Kuypers from the University Hospital Leuven will lead the trial in Belgium and is keen to start.

As inclusion is going well at this moment the trial will probably expand to 2000 participants. Therefore, help was asked from Spain and Turkey to increase inclusion. Currently, preparations are being made to also start the trial there.

Prof. Dirk Kuypers