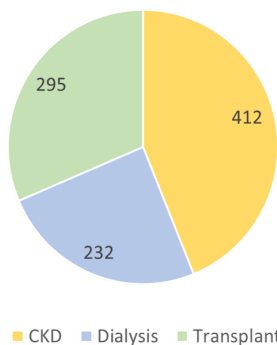


Recruitment and study progress

To date, 939 patients were screened and 863 patients were randomized.

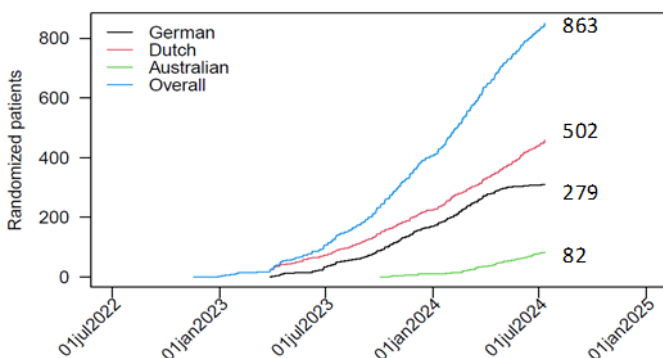
The diagram below shows the inclusion per subgroup. Currently, the CKD group is relatively large. Therefore, we would like to draw your attention to include especially dialysis patients.

Distribution over the three groups
Global



The diagram below shows the inclusion per country. Inclusion in the Netherlands continues steadily, good job! Germany has reached their major milestone of randomizing 250 participants and therefore stopped inclusion as arranged. Inclusion in Australia is currently steadily, to reach ultimately 250 patients. Nine sites from Belgium will hopefully soon be allowed to join, and we are still considering to expand the trial. Discussions are ongoing to add Singapore and Turkey.

Total Randomized patients



First endpoint meeting

On the 9th of July we had the first meeting with the Clinical Adjudication Committee (CAC). The CAC assesses the potential reported endpoints of hospitalization for heart failure. During this meeting the first potential reported endpoints for heart failure were discussed and the main conclusion was that additional information was needed for most of cases. Several sites have received therefore a separate request to provide additional data.

To minimize the number of requests for additional information in the future: we would like to emphasize that for each hospitalization SAE a discharge letter should be added to the form.

The Clinical Adjudication Committee would like to see for potential heart failure hospital admission information

- Admission note (information on anamnesis, physical examination and conclusion at the emergency room)
- Use of IV-diuretics
- Chest x-ray
- Dialysis dynamics (trends in dry and actual weight, volume of fluid removed during dialysis, weight at admission and at discharge etc) and adherence (were shortly before dialysis sessions skipped?)

REDCap topic of the month

SAE reporting

We would like to draw your attention to how to report a SAE. The Sponsor Team will review potential endpoints based on the SAE/AE of Special Interest reported in REDCap. To be able to do so it is important that required data fields are filled. Please ensure that all events that occur during the admission are linked to the original SAE and are not reported separately.

For example if a patient was admitted to hospital for potential heart failure, and the admission resulted in death. Then death should be reported within the same SAE and not as separate SAE.

Whishing you a great (summer) holiday!

