Newsletter

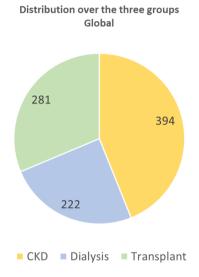
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Recruitment and study progress

We are happy to announce that currently more than 900 patients were screened and over 800 participants were randomized! **Great job!**

The diagram below shows the inclusion per subgroup:



Preparation is key!

We would like to emphasize that visit preparation is of utmost importance and will prevent last-minute errors/ questions.

In particular, the following study procedures are advised to prepare/verify well in time:

- ALEA dispensation study medication
- Cognitive substudy registration (Orikami)
- Questionnaires
- Biobanking

Reporting kidney transplantation endpoint in REDcap

We would like to draw your attention to the kidney transplant endpoint. In REDCap this event is part of the SAEs/AEoSI eCRF, however a kidney transplantation is no SAE. A paper SAE form is not warranted. Only the eCRF for this event should be completed. This can be applied in all three subgroups.

Change of subgroup during the trial

One of the unique aspects of the Renal Lifecycle trial is that participants can remain in the trial if the initial subgroup status changes. Participants who started in the CKD subgroup, can move to the dialysis group and even the transplant group during the trial. Do note that participants must meet the entry criteria of the initial subgroup during the randomization visit.

For example: if a dialysis participant receives a kidney transplant during the trial and has a GFR >45 mL/min/1.73m² after transplantation, the participant can remain in the trial. Study medication should be restarted in accordance with the study protocol.

Practical information site switch form (the Netherlands only)

As the first participant site switches are a fact, we would like to share additional information. If there are questions or uncertainties, please reach out the UMCG study team.

- Participants must sign the Patient Information Form (PIF) of the new site as part of the site switch procedure. Do note that this must be completed a few days before a scheduled dispensation/study visit. The signed PIF is required before data of the participant can be transferred to the new site within ALEA and REDcap.
- Kind reminder, please share the complete site switch forms within two months when informed about an upcoming site switch.

For example: if a participant moves from the UMCG to MCL, the team of MCL is asked to return the site switch form to the UMCG site team and the SD CRO with the additional information within two months.



