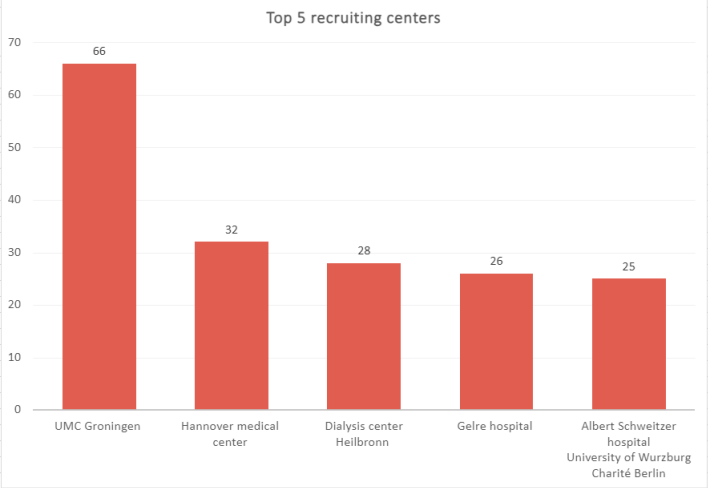
Newsletter

Issue 7· March 2024

Recruitment and study progress

The past month, we have enrolled over 75 new participants worldwide. Excellent work! In Australia the summer holidays have ended and inclusion is taking off, the first 40 participants have now been enrolled. The German investigators deserve a compliment. They are recruiting very well, and have randomized now approx. 250 participants. In the Netherlands, approx. 350 participants have been randomized. The top 5 recruiting centers are shown below.



DSMB

On the 26th of March the Data Safety Monitoring Board convened to discuss the progress of the Renal Lifecycle trial. The DSMB concluded that there are no comments regarding the progress nor the safety of the trial and that we can proceed with enrolling participants as planned.

Symposium— April 5th!

This week, the symposium about the Renal Lifecycle trial and optimization of cardio-and renoprotective treatment in patients with severe CKD will take place. We received many enthousiastic reactions and look forward to see you in Utrecht!

For those who did not register yet, you can still do so by sending an e-mail with your BIG-code and name to: renal.lifecycle.trial@umcg.nl.

Adverse Events of Special Interest

Please be reminded that Adverse Events do not need to reported in REDcap. However, Adverse Events of Special Interest (AEoSI) do need to be recorded to investigate study drug tolearibility in our vulnerable patient populations. These are: UTI, genital infections, significant hypoglycemia and diabetic keto-acidosis. Furthermore, please report Discontinuation Adverse Events (DAEs) and Serious Adverse Events (SAEs).

Updated KDIGO guideline

Recently, the new KDIGO CKD guideline has been published. This guideline indicates that SGLT2i can be prescribed to patients with diabetic and non-diabetic kidney disease with an eGFR >20 ml/min/ 1.73m^2. In the Renal Lifecycle trial the cut-off is ≤25 ml/min/ 1.73m^2. The Steering Committee has discussed this and decided that participants with an eGFR between 20-25 ml/min/ 1.73m^2 are still eligible. There is only one study, that included a limited number of patients in this eGFR range. We think therefore that additional evidence is needed. Local investigators are of course free not to include such patients.

FAQ

Per protocol it is allowed to combine the screening and randomization visits. If these visits are combined, please be aware that there should be recent lab data available to assess eligibility. Laboratory assessments per protocol can only be obtained after having received informed consent. Same day results OR historical data in the past 7 days with explicit and documented consent from the participant that this historical data can be used are allowed. In REDcap, the lab results should be entered for the screening as well as the randomization visit. Please note that more lab parameters should be determined for randomization than for screening.

Thank you!