Newsletter

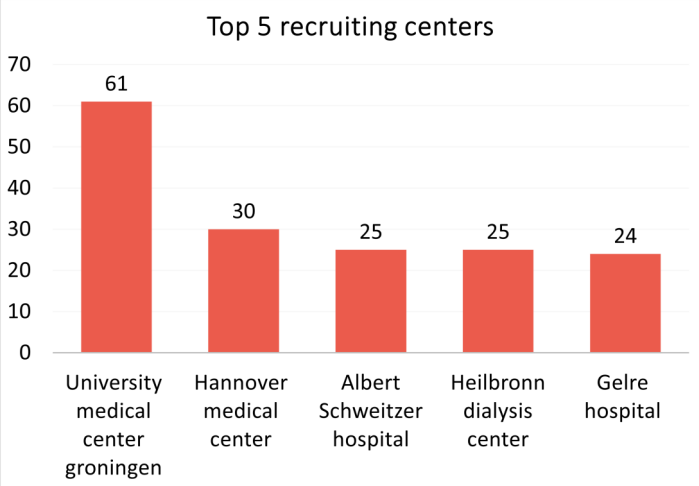
Issue 6· February 2024

RENAL LIFECYCLE TRIAL

Recruitment needed

Currently, 614 patients have been screened and as yet 518 patients randomized, with only few screen failures (<10%). New centers have been initiated. Now 68 centers are recruiting patients in the Netherlands, Belgium and Australia. The target is 1500 patients. The number of inclusions is growing, but needs attention, especially for dialysis and transplant patients. University Medical Centers are expected to include ±40 patients and the other hospitals 20-30 patients to make the trial a success. We as well as our main funder (the Dutch Kidney Foundation) are hoping for your support in this important trial.

So far, there are 16 reported endpoints: two patients died (all-cause mortality), three started chronic dialysis, five had a kidney transplantation and six were hospitalized for heart failure. Based on these numbers, the first meeting with the Clinical Adjudication Committee is scheduled.



Update information for the DSMB

The next meeting of the Data Safety Monitoring Board (DSMB) is scheduled on March 26th. The queries in Redcap need to be answered before this date to make sure that the database is as complete as possible to allow the DSMB to draw conclusions on safety and progress of the trial. Thank you in advance for replying!

Start SGLT-2 inhibitors for heart failure?

Several cardiologists started an SGLT-2 inhibitor as treatment for heart failure in patients in our trial. It is important to mention to these cardiologists that for patients with severe CKD (our patient groups) no evidence exists on the efffectiveness of SGLT2 inhibition. In the Renal Lifecycle trial this is one of the study questions. In the meantime it is our view that cardiologists should refrain from using SGLT2i for heart failure in such patients.

SAE form confusing, needing repair

On page two of the SAE form for the question “related to subject safety?” the option “no”’ can be filled in. This can be confusing as an SAE always relates to the patients safety. This aspect will be clarified in the new SAE form. In the new version ’Adjustment of trial subject information’ and ’modification of in/exclusion criteria’ are classified as ’cannot initially filled in by the site’. Please note that in the next weeks new SAE templates will be distributed.

Symposium on our trial

Thanks to those who registered for the symposium about the initial results of the Renal Lifecycle trial and optimization of cardio-and renoprotective treatment that is scheduled on April the 5th. We look forward to see you in Utrecht and share experiences !

For those who did not register yet, the program can be found on www.renal-lifecycle.com. You can register by sending an e-mail with your BIG-code and name to: renal.lifecycle.trial@umcg.nl.

We hope to see you !

Questions regarding biobanking ?

We have a general e-mail adress to reach out to for biobank-related questions: biobank@kff.umcg.nl.