Newsletter

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RENAL LIFECYCLE TRIAL

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From the trial coordinator
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Initially, the Renal Lifecycle trial started as a national study in the Netherlands. Funding has been obtained via the Dutch Kidney foundation derived from a legacy of a private person. The pragmatic trial design and unique study population make the trial very interesting and we're are excited that the trial will be expended to Belgium (approx. 10 centres), Australia (15-19 centres) and most likely also Germany.

In the meantime we have obtained ethics approval to start the trial in the Netherlands! A little over 30 sites received approval as participating centre. Meanwhile, the regional teams in Belgium (Leuven), Germany (Wurzburg) and Australia (Sydney) are working on the regulatory preparations. We aim to complete the study preparations by the end of the Augustus to facilitate start of the trial by early September. We aim to have the study up and running by the end of the year for most participating centres in the Netherlands.

At last, sub-studies have been proposed to further increase the scientific value of the trial. The upcoming amendment will include two cardiac sub-studies: an cardiac MRI sub-study (250 participants) and a cardiac echocardiography sub-study (100 participants). The details of the sub-studies will be shared once ethics approval has been obtained.

The Renal Lifecycle trial is a pragmatic, investigator–initiated, international, double-blind, randomized study to assess the effect of dapagliflozin on renal and cardiovascular outcomes in patients with severe CKD.

Expected timelines

Ethics approval NL	30 Jun 2022
First site activated	End of Aug 2022
First screening	Sep 2022
First patiënt randomised	Sep/Oct 2022

Important

To ensure a swift initiation of all participating centre, we would like to

- note that all local study team members require a valid GCP or BROK certificate
- consider which colleagues require access to ALEA for randomisation and REDcap for data entry.
- inform you that the investigator site file (ISF) will be provided, digitally, before the initiation/kick-off meetings (Sep/Oct)
- inform you that template documents documents (e.g. delegation log) are part of the ISF

THANK YOU!

At last, compliments and a big thank you for all efforts and commitment during the start-up period. We will keep collaborating on getting all required documents and agreements in place as we are eager to start enrollment of patients!