

Newsletter

Issue 2 · Summer 2023



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.

The first 100 participants

Last month we reached an important milestone, many participants agreed to participate and completed the screening visit and more than 100 participants are successfully randomized!

The graph on the second page displays the overall inclusion and the inclusion per subgroup.

Adding sites

We are very happy to see that the study is going well. More and more sites are initiated, both in the Netherlands as well in Germany. The first sites in Australia have been initiated and will enrol the first participants as soon as the study medication arrives.

Adding substudies

In addition, in April the Ethics Committee of the UMCG approved the protocol amendment to include the cardiac MRI and echo sub-studies. These studies are led by doctors Sunil Badve and Clare Arnott from Sydney, Australia, and by doctors Marc Vervloet and Lily Jakulj from Amsterdam UMC. Several sites in the Netherlands and Australia will start with these substudies to collect more evidence regarding the mechanisms underpinning the cardioprotective effects of SGLT2 inhibition in this study population.

For more details: see Annex B of study protocol version 7.

Congratulations to the top 6 recruiting centers

1. University Medical Center Groningen
2. Gelre Hospital
3. Albert Schweitzer Hospital
4. Franciscus Gasthuis and Vlietland
5. University Clinic Wurzburg
6. MC Leeuwarden / Meander MC

Cognitive function testing

At the moment we are preparing a new protocol amendment to include a cognitive function test to further enhance the potential of the Renal Lifecycle trial. There are some preliminary data that SGLT2 inhibitors would preserve cognitive functioning. Participants will be asked to complete the Digit Symbol Substitution Test via a smartphone (android/iOs) or tablet (iOs) using an app developed by the company Orikami. They can do this at home, or in case patients have no smart phone or no app skills, they can do the test in the clinic with help of a nurse. The test is self-explanatory, needs no training of personnel and costs only 2 minutes. After approval from the Ethics Committee, we will start with a testing phase in the UMCG and will extent to other sites thereafter.

Number of recruiting sites per country

The Netherlands: 41

Australia: 17

Germany: 16

Belgium: 0*

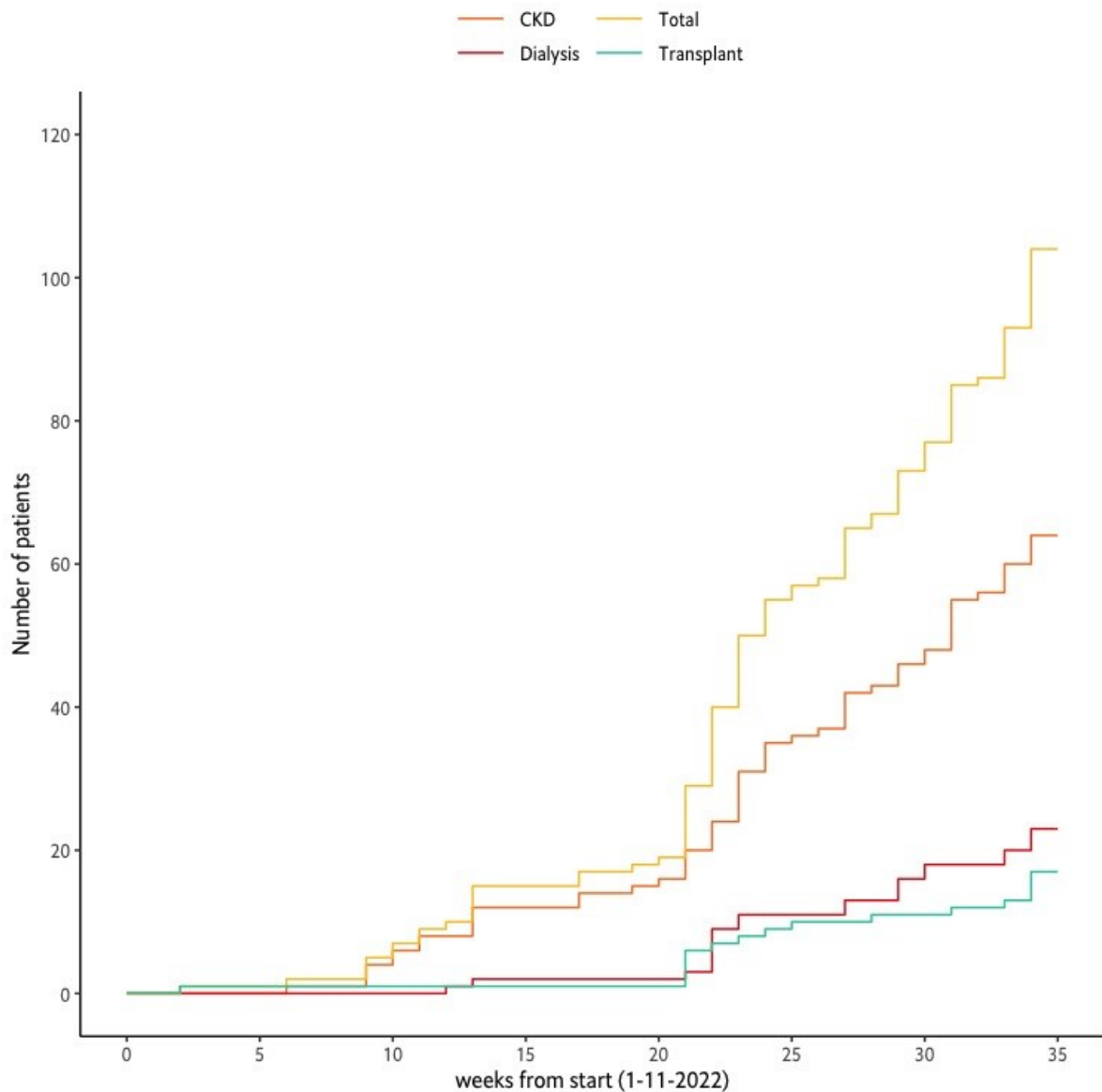
* new sites can only be initiated after switching the study to the new Clinical trial regulations—expected fall 2023

THANK YOU!

Compliments and a big thank you for all your efforts and commitment during the start-up period. We are very happy to see that there is such willingness to participate. Well done!

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Patient screening numbers from start study until June 2023

Screenings and randomizations

Total participants screened	126	CKD	66
Total participants randomized:	104	Dialysis	23
		Transplant	15

You can find more information and/or contact us by using the following links:



www.renal-lifecycle.com



renal.lifecycle.trial@umcg.nl