Newsletter

Issue 8· April 2024

Recruitment and study progress

To date, more than 750 participants have completed their screening visit. Thank you for all the hard work and keep up this good work !

In particular we would like to **congratulate the German participating sites**. They have reached a major milestone of randomizing 250 participants. Fantastic!

Of note, the trial is powered with a recruitment target of around 1500 randomized participants to reach 468 endpoints for the total population. If recruitment is going well, we have approval from Astra Zeneca to extend the trial to 2000 participants. This will increase the overall power of the trial, and more importantly, this would provide also more power to reach definitive conclusions in each of the three subgroups of patients. This would increase the clinical impact of our trial!

Cognition test SDMT

Please be informed that several updates have been implemented to improve the ease of conducting the cognitive function test:

- It is no longer required to add an organization name during the log-in procedure.
- Date of birth of the participant: this field should remain empty.
- New customer support link: **customer.support.orikami.nl**

Symposium

On April 5th, a symposium was organized concerning optimization of cardio-and renoprotective treatment in patients with advanced chronic kidney disease. It was attended by more than 100 people. We would like to thank all attendees for their presence and their enthusiastic input. Recordings of the presentations will be available on the website of the Renal Lifecycle Trial.

Global coordinating team: general questions and/or remarks

The Renal Lifecycle team is coordinated by the UMCG in the Netherlands and Belgium, by the Clinical Trial Office of University of Würzburg in Germany and by the George Institute in Australia. For general questions and/or remarks, please address these to:

NL/BE: renal.lifecycle.trial@umcg.nl
Germany: clinicaltrialoffice@ukw.de
Australia: renal_lifecycle@georgeinstitute.org.au

The importance of reporting (potential) endpoints – also when in doubt…

The Renal Lifecycle Trial is an endpoint-driven clinical trial. As a result, the trial will only end once we reach our target of 468 reported and confirmed endpoints. The main endpoints that can be reached are all-cause mortality, kidney failure and hospitalization for heart failure. All potential endpoints should be reported in the eCRF. Clinical events that may be related to hospitalization for heart failure are evaluated by the Clinical Adjudication Committee.

To prevent underreporting – please report all potential endpoints in the eCRF. In case of hospitalization for overfilling, please report this, even when you think it was renal overfilling. The Adjudication Committee will decide centrally whether it is a heart failure endpoint or not. Please also bear in mind that a participant can reach more than one endpoint.