Newsletter

Issue 9· May 2024

RENAL LIFECYCLE TRIAL

Change in inclusion criteria

Residual diuresis dialysis population

We would like to draw your attention to the e-mail that was sent on the 15th of May about the Note to File for the dialysis population.

As per protocol version 9, the specific inclusion criteria for dialysis patients states that they should also have a residual diuresis of ≥500 ml/24h.

The Trial Steering Committee decided that **this mandatory additional criterion of residual diuresis ≥500ml/24h will be removed for dialysis patients**. This has been changed as many dialysis patients have less diuresis, which complicates inclusion. Moreover, dropping this criterion will increase the external validity of the trial.

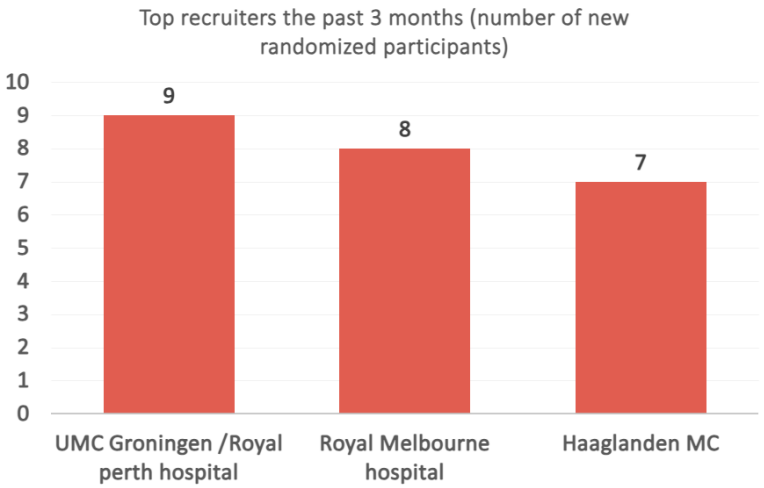
24-hour urine collection not mandatory

Additionaly, **collection of a 24 hour urine is not mandatory anymore.** In case the patient really does not want to collect 24 hour urine, an early morning void or spot urine can be collected (in this specific order of preference). Please keep in mind to do this consistently for each participant (thus either only early morning void, only urine spot or only 24h urine collection during the follow-up of the participant) and note this in the eCRF (which shows an option where you can fill this in).

Recruitment and study progress

To date, 853 participants were screened and 759 participants were randomized. Compared to last month, this indicates that 70 new participants have completed their screening visit and 71 participants were succesfully randomized.

The inclusion of the dialysis population is still lagging behind. With the change in inclusion criteria for the dialysis population we hope this will ease inclusion for this population (see column on the left).



Study medication dispensation

A few incidences have been reported for deviations during study medication dispensation visits. We would like to draw your attention to the following:

1. Please ensure that the ALEA patient ID is verified before completing the dispensation form in ALEA. As the REDcap and ALEA patient IDs might not match, this could cause an deviation
2. Please ensure that the kit numbers are properly verified before handing out to the participant.
3. At last, some potential dispensation errors are pre-programmed within ALEA and will show up as notification during randomisation. E.g. if a visit is out of window. If you receive an error notification, reach out to your national coordinator to verify what might be the issues before overruling the automatic error notification.