Newsletter

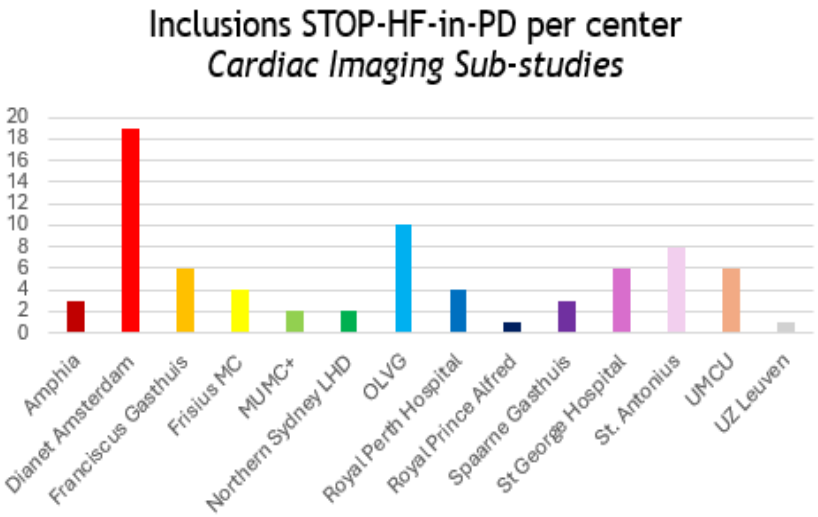
Issue 22· August 2025

Study progress

So far, a total of **1420** participants has been successfully randomized. We are pleased to share that the first Spanish site was initiated last month and is expected to begin inclusion shortly. Ten more Spanish sites will start in the coming weeks. Recruitment is also progressing in Belgium, where the UZ Leuven with investigator Dirk Kuypers has enrolled the first 10 participants during the last month. Collectively, we are advancing towards our target of enrolling 1,750 to 2,000 participants.

The Stop-HF-in-PD sub- study

In the STOP-HF-in-PD sub-study of the Renal Lifecycle Trial, it is investigated what the effect of dapagliflozin is on cardiac function in PD patients. This is of interest as accumulating clinical evidence suggests that SGLT2 inhibitors has direct effects on the heart. This is remarkable, because it is not known that cardiac tissue expresses the SGLT2 receptor. Whether this assumption is correct can be investigated in dialysis patients, because these patients have hardly any functioning nephrons with proximal tubular SGLT2 receptor expression left. PD patients were chose, because these are more stable with respect to fluid status as HD patient. This has the additional advantage that the possible protective effect of dapagliflozin on peritoneal function can be assessed.



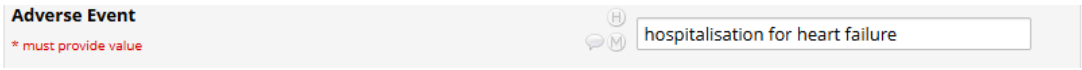
The STOP-HF-in-PD study is conducted not only in the Netherlands, but also in Australia and Belgium. Recently, the first patient was enrolled at UZ Leuven, and we look forward to the first inclusions from UZ Brussels and UZ Antwerp.

Overall inclusion is progressing well. So far, **75** out of a total of **100** patients have been enrolled — a great achievement for which we would like to thank all participating centres!

If you have questions about the study, please contact research-physician Micky Karsten or project leader Lily Jakulj via stophfinpd@amsterdamumc.nl.

Clarification needed for SAE descriptions in REDCap

The data management team noticed that for some participants, the '**description of event**' field in REDCap only includes the term 'hospitalized'. While this indicates that a SAE occurred, it does not provide sufficient detail for proper documentation. We kindly ask you to specify the reason for hospitalization, for example: 'hospitalization for heart failure' (see example below). Providing this information helps data management to avoid queries and ensures quality of safety reporting.



Patient retention in the trial

Keeping patients in a clinical trial is pivotal for its representativeness and therefore for its scientific quality. In our trial **145** participants have discontinued after randomization, of which **47** due to mortality. This means that **only 6.9 %** of the participants in the overall trial withdrew for other reasons, such as personal choice or moving home. This is excellent compared to other trials. Let's maintain this high level of participation an important priority.