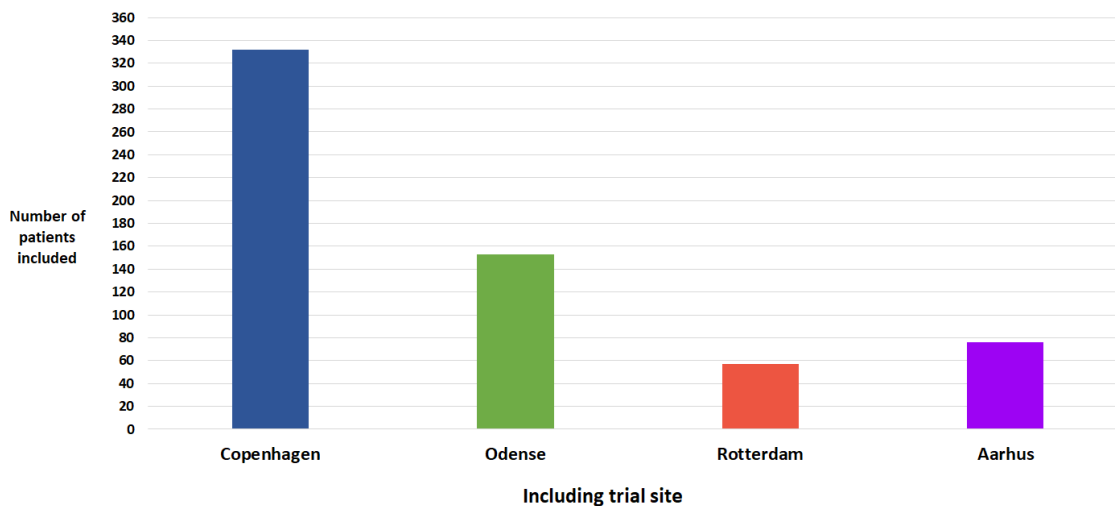
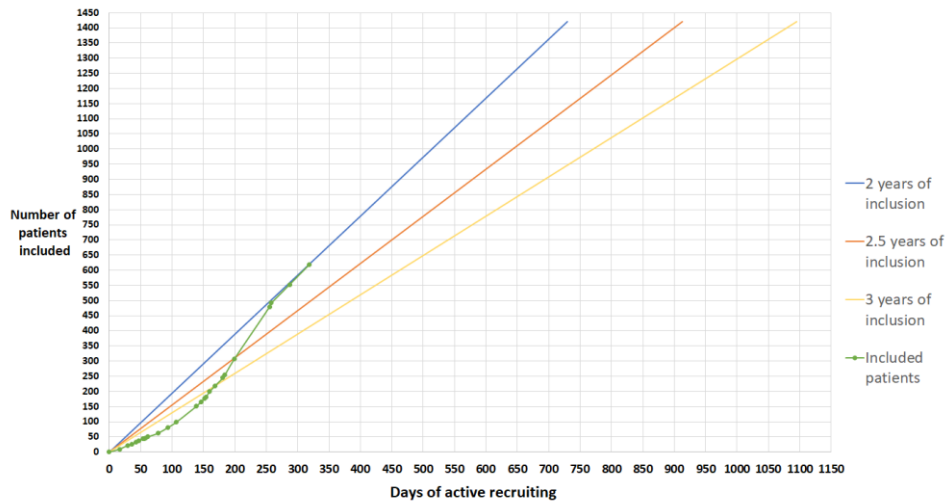
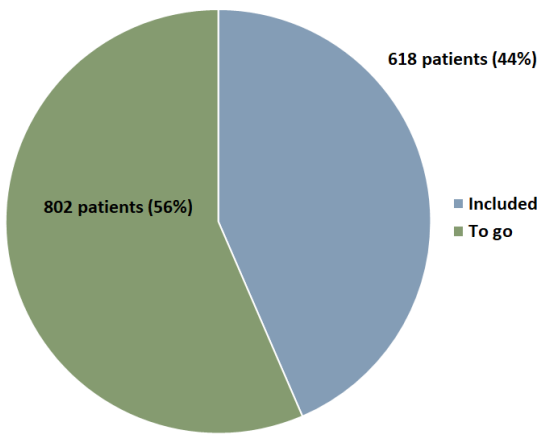




Dear all

- We have received response from the Data Monitoring and Safety Committee on the first interim analysis. The committee recommended continuation of the trial. In addition, they requested a CONSORT flowchart for the second interim analysis. We will soon contact each centre regarding screening of eligible patients and missed inclusions.
- We are preparing documents for the authorities in Antwerp, Belgium in order to begin recruitment in 4-6 months.
- Soon we will transfer the first payments (150 euro/patient) for trial participants with a primary outcome assessment registered in REDCap.



Focus point

We still need focus on completing the data collection sheets and avoiding major protocol violations. Regretfully, we see a number of patients that did not receive the allocated treatment for the entire 8 hour intervention resulting in major protocol violations.

With best regards

Jacob Steinmetz (sponsor)

&

Tobias Arleth (c. investigator)