

Annex section D EudrCt end of trial form.

During the course of our trial we encountered several unexpected issues during the GMP production of the ¹¹C-telmisartan tracer resulting in low yields of the end product. Those issues were always thoroughly investigated and resolved for that moment. Unfortunately productions with low yields keep happening. That's why we concluded that it's not feasible to perform PET imaging studies with this tracer.

The yield of an ¹¹C Telmisartan synthesis is only known just before the moment of scheduled injection to the study patient. That's why the study patients already received venous and arterial lines on the occasions where the yields were to low. And in some cases they had discontinued their renin-angiotensin system blocker 2 weeks prior to the scheduled study day. If the tracer wasn't injected, no further study activities were done. Those occasions have therefore not led to other safety issues than some inconvenience from the invasive procedures for the study participants. Also, since our study only consists of one study day, stopping the trial will have no impact on the safety of the patients who are already included in the study, but have not yet been scheduled for the study measurements.

This feasibility study aimed to include 9 subjects, at the time of early termination 5 had completed the study. We will analyze their data, focusing on the unique pharmacokinetic and pharmacodynamic information on telmisartan it will provide us. Since the synthesis of ¹¹C-Telmisartan turned out to be not stable enough for use in patients, we cannot use the data from this study to use in further patient studies with this tracer, one of the other objectives of this feasibility study.

5.1.2.e

5.1.2.e

9 Oct 2020
Groningen
The Netherlands