Duplex

Status completed: no inclusion

S-nummer: S63362 Phase III study
Principal Investigator: prof. dr. Björn Meijers

Title: A randomized, multicenter, double-blind, parallel, active-control study of the effects of sparsentan, a dual endothelin receptor and angiotensin receptor blocker, on renal outcomes in patients with primary focal segmental glomerulosclerosis (FSGS).

Purpose and rationale: 1) Efficacy: to determine the long-term nephroprotective potential of treatment with sparsentan as compared with an ARB in patients with primary and genetic FSGS. 2) Safety Objective: to assess the safety and tolerability of sparsentan by double-blind monitoring of safety endpoints. 3) Open-Label Objective: to assess the long-term efficacy, safety, and tolerability of open-label sparsentan in patients with FSGS.

Primary endpoint: The slope of eGFR over approximately 2 years of randomized treatment assessed at the final analysis.

Medication/treatment: Sparsentan (ARB) (initial dose of 400 mg daily for 2 weeks, titrating up to a target dose of 800 mg daily) or an active control (irbesartan; initial dose of 150 mg daily for 2 weeks, titrating up to a target dose of 300 mg daily). (Randomization 1:1)

Duration of study: 112 weeks randomized study with an open-label extension of up to 156 weeks. Thus, a total study duration of up to 268 weeks.

Results: The results are currently under investigation. As soon as these are available, they will be shared.