Falcon

Status completed: no inclusion

S-nummer: S63102 Phase III study
Principal Investigator: prof. dr. Bert Bammens

Title: A phase 3 trial of the efficacy and safety of bardoxolone methyl in patients with autosomal dominant polycystic kidney disease.

Purpose and rationale: To evaluate the safety, tolerability, and efficacy of bardoxolone methyl in qualified patients with ADPKD compared to placebo. Bardoxolone methyl has consistently improved parameters of renal function in other studies by taking influence on inflammation processes, on mitochondrial function and on imbalances between the production of free radicals and the ability of the body to counteract. As a result, bardoxolone methyl is considered to delay disease progression in patients with ADPKD.

Primary endpoint: Off-treatment change from baseline in eGFR at Week 108.

Medication/treatment: Bardoxolone methyl (Nrf2 activator), administered orally at 5, 10, 20, or 30 mg or a matching placebo.

Duration of study: Approximately 112 weeks (or 26 months), consisting of 24 visits.

Results: This study was terminated early. The researchers did publish a limited study report indicating that the medication was safe. No clear therapeutic effect of the treatment was observed. (See attached document “studie resultaten”.)