aHUS Registry

Status ongoing: active inclusion

s-nummer: S55516 Phase IV study
Principal Investigator: prof. dr. Kathleen Claes

Title: An observational, non-interventional, multi-center, multi-national study of patients with atypical hemolytic-uremic syndrome (ahus registry).

Purpose and rationale: The study is designed to collect information on the long-term safety and effectiveness of Soliris and Ultomiris, and to collect information on the long-term clinical manifestations of thrombotic microangiopathy (TMA) complications of aHUS, as well as other outcomes in patients with aHUS, regardless of treatment approach.

Primary endpoint: The proportion of patients who experience the following events: serious infections, including Aspergillus infections and infections due to encapsulated bacteria such as N. meningitidis, sepsis, infusion reactions, immunogenicity/ADA response, hepatic impairment, renal impairment, malignancy, and death (from any cause), and TMA complications of aHUS after Soliris or Ultomiris discontinuation.

Medication/treatment: No study drug will be administered in this observational study. Treatment decisions are independent of patient participation in the study and according to clinical practice.

Duration of study: At least 5 years or longer, without any additional study visits.

Key inclusion criteria:
- Male or female patients of any age, including minors
- Clinical diagnosis of aHUS, regardless of treatment approach
- Patients with or without an identified complement pathogenic variant or anti complement factor antibody
- ADAMTS13 > 5% (if performed)

Key exclusion criteria:
- HUS only due to Shiga toxin-producing Escherichia coli (STEC)