DRAIHA – study

Data **R**egistry of **A**uto**I**mmune **H**emolytic **A**nemia, to improve diagnostic testing for the development of personalized treatment protocols in AIHA patients.

Short title: The DRAIHA study: Data Registry of AutoImmune Hemolytic Anemia
Sponsor: Sanquin
ClinicalTrials.gov ID: NCT04024202

Study population:

1. Patients, from the age of 3 months, with a positive DAT a positive eluate and signs of hemolysis and patients with a positive DAT for complement only with a negative eluate but with signs of hemolysis.
2. Blood donors with a positive DAT and a positive eluate and/or clinically relevant cold autoantibodies.

Type of study:

This is an observational cohort study. Via a prospective centralized clinical data collection and evaluation of (new) laboratory tests, we will study a group well-characterized patients with AIHA and DAT positive blood donors without AIHA. At diagnosis and after 1-1,5 year, 36 ml of blood and a urine sample will be additionally collected for experimental diagnostic testing. At the same time points the coordinating investigator will collect clinical data by a structured report form in the online databank named Castor. In patients aged 3 months until 16 years old, no extra blood or an urine sample will be collected. These patients will only be registered in the databank and experimental diagnostic testing will be performed on residual blood obtained from routine diagnostic testing.

Study objectives:

Primary Objectives:

1. Determine the correlation between the specification of a positive direct antiglobulin test and/or red blood cell autoantibody and the clinical course in patients with AIHA.
2. Determine the contribution of standard laboratory and experimental test results to predict the clinical course and treatment response of AIHA.

Secondary Objectives:

1. Determine diagnostic predictors for safe and efficient blood transfusion in AIHA patients.

Determine the clinical consequences of DAT-positivity in blood donors to develop a clinical guideline for follow-up and counseling.

Subject eligibility criteria:

Key Inclusion criteria:

1. Patients older than 3 months
2. Patients with a positive DAT, a positive eluate and signs of hemolysis
3. Patients with a positive DAT with complement only, negative eluate, but with signs of hemolysis

4. Donors with a (repeatedly) positive DAT and a positive eluate and/or clinically relevant cold auto-antibodies
5. Sufficient comprehension of the Dutch language
6. Signed informed consent by patient and/or parent/caretaker or donor

Key Exclusion criteria:

Prior inclusion in the DRAIHA study

Status/Participating sites:

Open in Radboud UMC, Nijmegen
Open in Amsterdam UMC, location AMC
Open in St. Antonius Ziekenhuis, Nieuwegein
Open in Isala, Zwolle
Open in OLVG, Amsterdam
Opening in LUMC, HagaZiekenhuis, Jeroen Bosch Ziekenhuis, Erasmus MC, Maastricht UMC, UMC Utrecht, Spaarne Gasthuis, Twente Medisch Centrum, Sanquin

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