Swiss Soliris® aHUS Reimbursement Registry SSaRR: Observational registry of patients suffering from atypical Hemolytic Uremic Syndrome (aHUS) who are treated with Soliris® (Eculizumab)

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Study Ongoing

Administrative details

EU PAS number

EUPAS37301

Study ID

40071

DARWIN EU® study

No

Study countries

Switzerland

Study status

Ongoing

Research institutions and networks

Institutions

Hôpitaux Universitaires de Genève (HUG)

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Institution

Inselspital

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Institution

Hôpitaux Universitaires de Genève Switzerland, Centre Hospitalier Universitaire Vaudois Switzerland, Inselspital Bern Switzerland, Kantonsspital Frauenfeld Switzerland, Kantonsspital Luzern Switzerland, Universitätsspital Basel Switzerland, Kantonsspital

Aarau Switzerland, Universitätsspital Zürich Switzerland, Kantonsspital Chur & Kantonsspital St. Gallen Switzerland, Ente Ospedaliero Cantonale Bellinzona Switzerland

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jan Bolten

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/11/2018

Study start date

Actual: 06/11/2018

Data analysis start date

Actual: 17/09/2019

Date of final study report
Planned: 31/10/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alexion Pharma GmbH

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

Collection of medical information related to the initiation and continuation of therapy for patients suffering from atypical Hemolytic Uremic Syndrome (aHUS) who are treated with Soliris (Eculizumab).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational registry

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AA25) eculizumab

eculizumab

Medical condition to be studied

Atypical haemolytic uraemic syndrome

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

20

Study design details

Outcomes

parameters:Platelet-countHemoglobin level (or Haptoglobin level)Presence of schistocytesLDH-levelNumber of plasma interventionsOrgan functions/complicationsQuality of Life

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Data analysis plan

The statistical evaluation of will be laid out according to the reporting requirements for the FOPH/BAG. Mainly descriptive statistics will be applied.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Observational registry and retrospective collection of patient data

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No