Swiss Soliris® and Ultomiris® Reimbursement Registry SSURR: An observational registry for capturing data of patients suffering from paroxysmal nocturnal hemoglobinuria (PNH) who are treated with Soliris® (eculizumab) or Ultomiris® (ravulizumab)

First published: 22/09/2020

Last updated: 27/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS37218

Study ID

37332

DARWIN EU® study

No

Study countries

Switzerland

Study description

Swiss Soliris® and Ultomiris® Reimbursement Registry SSURR: An observational registry for capturing data of patients suffering from paroxysmal nocturnal hemoglobinuria (PNH) who are treated with Soliris® (eculizumab) or Ultomiris® (ravulizumab). The participating centres are determined by FOPH/BAG and per requirements a study report is submitted every year, usually at the last quarter.

Study status

Ongoing

Research institutions and networks

Institutions

Hôpitaux Universitaires de Genève (HUG)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Inselspital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University Hospital of Basel

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Hôpitaux Universitaires de Genève Switzerland, Centre Hospitalier Universitaire Vaudois Switzerland, Inselspital Bern Switzerland, Kantonsspital Luzern Switzerland, Universitätsspital Basel Switzerland, Kantonsspital Aarau Switzerland, Universitätsspital Zürich Switzerland, Kantonsspital Chur (for Ultomiris only) Switzerland, Ente Ospedaliero Cantonale Bellinzona Switzerland, Kantonsspital St. Gallen 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: 29/11/2011

Study start date

Actual: 19/01/2012

Data analysis start date

Actual: 28/12/2012

Date of final study report

Planned: 20/12/2024

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 initiation and continuation of therapy for patients diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) and treated with Soliris® or Ultomiris® in Switzerland.

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

(L04AA43) ravulizumab

ravulizumab

Medical condition to be studied

Paroxysmal nocturnal haemoglobinuria

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

Study design details

Outcomes

hematological parameters, LDH value, PNH symptoms such as abdominal pain, chest pain, dyspnoea and pain requiring medical intervention, performance on a "quality of life" scale, need for transfusions, thrombotic events, occurrence of renal failure and pulmonary arterial hypertension

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