C1 inhibitor Treatment Registry to assess the Safety and Immunological Profile of Ruconest in the treatment of HAE Attacks (Ruconest Registry)

First published: 29/08/2014

Last updated: 10/04/2025

Study | Finalised

Administrative details

EU PAS number

EUPAS7375

Study ID

38421

DARWIN EU® study

No

Study countries

Bulgaria

Croatia

France

Germany
Hungary
Italy
Norway
Poland
Slovakia
Slovenia
Sweden

Study description

Non-interventional treatment Registry of HAE patients treated with C1 inhibitor, either plasma-derived (pdC1INH) or the recombinant human form (Ruconest)

Study status

Finalised

Research institutions and networks

Institutions

Pharming Technologies

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anurag Relan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/10/2011

Actual: 06/10/2011

Study start date

Planned: 06/10/2011

Actual: 06/10/2011

Data analysis start date

Actual: 11/12/2024

Date of final study report

Planned: 31/12/2021

Actual: 24/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pharming Technologies BV

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To observe adverse events and insufficient efficacy, and to assess the immunological profile following single and repeated treatment with Ruconest in patients diagnosed with HAE

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Medicinal product name

RUCONEST

Study drug International non-proprietary name (INN) or common name

CONESTAT ALFA

Anatomical Therapeutic Chemical (ATC) code

(B06AC) Drugs used in hereditary angioedema

Drugs used in hereditary angioedema

(B06AC04) conestat alfa

conestat alfa

Medical condition to be studied

Hereditary angioedema

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

300

Study design details

Outcomes

Incidence of AEs reported per patient after single or repeated treatment with Ruconest or plasma-derived C1 inhibitor, Incidence of positive immunological test findings after treatment with Ruconest

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Data analysis plan

Incidences of patients with ADRs (globally, on preferred term and system organ class level) will be calculated for each Safety Analysis Set, 2-sided 95% confidence intervals will also be given.
In addition, incidences of patients with ADRs for each treatment number as well as overall percentages of treatments with ADRs will be given.
The number of treatments will be counted by patient and described by frequencies for each Safety Analysis Set.
The mean time between treatments (i.e. ratio of time under observation relative to number of treatments) will be described on a metric scale.
Efficacy will be described by frequencies for the overall assessment.
The statistical analysis will be descriptive and consist of frequency distributions (frequencies and percentages) for categorical variables, and descriptive statistics (mean, median, standard deviation, minimum, maximum, and number of observations) for quantitative variables, given for each Safety Analysis Set.

Documents

Study results

C1 1412 Ruconest Registry Report summary of results version 1.0 08APR2025.pdf (168.03 KB)

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

Prescription event monitoring, Exposure registry

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