

# 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

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### Study ID

38421


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### DARWIN EU® study

No

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### Study countries

 Bulgaria


 Croatia

 France

 Germany

 Hungary

 Italy

 Norway

 Poland

 Slovakia

 Slovenia

 Sweden

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## Study description

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

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Pharming Technologies

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### **Study institution contact**

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Study contact

[m.boshuizen@pharming.com](mailto:m.boshuizen@pharming.com)

### **Primary lead investigator**

Anurag Relan

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 06/10/2011

Actual: 06/10/2011

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### **Study start date**

Planned: 06/10/2011

Actual: 06/10/2011

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### **Data analysis start date**

Actual: 11/12/2024

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### **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

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### **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

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**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

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**Non-interventional study design, other**

Prescription event monitoring

## Study drug and medical condition

**Medicinal product name**

RUCONEST

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

CONESTAT ALFA

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**Anatomical Therapeutic Chemical (ATC) code**

(B06AC) Drugs used in hereditary angioedema

Drugs used in hereditary angioedema

(B06AC04) conestat alfa

conestat alfa

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### **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)
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### **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)

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## 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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

## **Data characterisation conducted**

No