

# A non-interventional, post-authorization safety study (PASS) to evaluate long-term safety of anakinra (Kineret®) in patients with systemic juvenile idiopathic arthritis

**First published:** 26/08/2019

**Last updated:** 14/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS28378

### Study ID

33063

### DARWIN EU® study

No

### Study countries

- Croatia
- Denmark
- France

- Germany
- Greece
- Hungary
- Israel
- Italy
- Latvia
- Netherlands
- Norway
- Romania
- Saudi Arabia
- Spain
- Switzerland

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### **Study description**

An international, non-interventional, single-armed, pharmacovigilance registry study on long-term safety of Kineret utilizing already available data from the ENCePP certified Pharmachild JIA registry.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

[IRCCS Istituto Giannina Gaslini, Pediatric Rheumatology International Trials Organisation \(PRINTO\)](#)

Italy

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

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

**Institution**

**Not-for-profit**

Multiple centres: 20 centres are involved in the study

## Networks

### Paediatric Rheumatology International Trials Organisation (PRINTO)

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary

- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- United Kingdom

**First published:** 05/10/2022

**Last updated:** 06/10/2022

**Network**

**ENCePP partner**

## Contact details

### **Study institution contact**

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**Study contact**

[nicolaruperto@gaslini.org](mailto:nicolaruperto@gaslini.org)

**Primary lead investigator**

Ruperto Nicola

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 29/05/2019

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**Study start date**

Actual: 15/12/2011

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**Data analysis start date**

Actual: 01/03/2019

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**Date of final study report**

Planned: 15/11/2019

Actual: 15/11/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Swedish Orphan Biovitrum AB (publ)

## Study protocol

## 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)

## Other study registration identification numbers and links

ClinicalTrials.gov Identifier: NCT03932344

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

Disease /health condition

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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

Other

**If 'other', further details on the scope of the study**

Pharmacovigilance

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The endpoints are: • The occurrence of non-serious AEs of at least moderate severity and serious AEs (SAEs), including MAS as an ESI. • The duration of Kineret treatment in a real-world setting. • The reasons for Kineret treatment discontinuation.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Single-armed, pharmacovigilance registry study

## Study drug and medical condition

**Medicinal product name**

KINERET

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**Medical condition to be studied**

Juvenile idiopathic arthritis

## Population studied

**Short description of the study population**

Male and female patients with a diagnosis of systemic juvenile idiopathic arthritis (SJIA) as per the International League of Associations for Rheumatology (ILAR) classification criteria included in the Pharmachild JIA registry study and who were ever treated with Kineret subsequently to SJIA diagnosis were included in the study.

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**Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

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**Estimated number of subjects**

306

## Study design details

**Data analysis plan**

Patient characteristics at baseline will be summarized and presented. The analysis will include calculation of unique incidence rates (with 95% CI) and incidence proportions of each reported term of non-serious AE (moderate and severe) and SAE. A patient may contribute with multiple events of the same AE

term. AE specific incidence rates and proportions will be presented overall for the whole study period and also by time windows defined with reference to the first dose of Kineret following a SJIA diagnosis. Analyses of sub-populations with long-term Kineret treatment will enable descriptive comparisons of incidence early in the treatment cycle and incidence resulting from long-term treatment. This study will pay a special interest to the incidence of MAS. Summary statistics for the duration of Kineret treatment will be presented overall and by time window. The reasons for Kineret treatment discontinuation will be summarized with number and percentage.

## Documents

### **Study results**

[Sobi.ANAKIN-302 Clinical Study Report FINAL version 15 Nov 2019\\_Redacted.pdf \(984.26 KB\)](#)

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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 source(s)**

PHARMACOVIGILANCE IN JUVENILE IDIOPATHIC ARTHRITIS PATIENTS  
(PHARMACHILD) TREATED WITH BIOLOGIC AGENTS AND/OR METHOTREXATE.

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**Data source(s), other**

Pharmachild - Juvenile idiopathic arthritis (JIA)

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**Data sources (types)**

[Disease 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

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## Data characterisation

**Data characterisation conducted**

No