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

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.

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

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Network ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ruperto Nicola

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/05/2019

Study start date

Actual: 15/12/2011

Data analysis start date

Actual: 01/03/2019

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

Sobi.ANAKIN-302 Clinical Study Protocol FINAL version 1 13 Mar 2019_Redacted.pdf(197.21 KB)

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)

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

Study type:

Non-interventional study

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

Main study objective:

The endpoints are:• The occurrence of non-serious AEs of at least moderate severity andserious 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

Non-interventional study design, other

Single-armed, pharmacovigilance registry study

Study drug and medical condition

Name of medicine

KINERET

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.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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 (moderateand severe) and SAE. A patient may contribute with multiple events of thesame AE

term. AE specific incidence rates and proportions will be presentedoverall for the whole study period and also by time windows defined withreference to the first dose of Kineret following a SJIA diagnosis. Analyses ofsub-populations with long-term Kineret treatment will enable descriptivecomparisons of incidence early in the treatment cycle and incidence resultingfrom 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 presentedoverall and by time window.The reasons for Kineret treatment discontinuation will be summarized withnumber and percentage.

Documents

Study results

Sobi.ANAKIN-302 Clinical Study Report FINAL version 15 Nov 2019_Redacted.pdf(984.26 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 source(s)

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

Data source(s), other

Pharmachild - Juvenile idiopathic arthritis (JIA)

Data sources (types)

Disease 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