A non-interventional, post authorization safety study (PASS) to evaluate the safety of Kineret in the treatment of Cryopyrin Associated Periodic Syndromes (CAPS) in routine clinical care with regard to serious infections, malignancies, injection site reactions, allergic reactions and medication errors, including re-use of syringe. Sobi.Anakin-201 (PASS Kineret CAPS)

First published: 21/08/2014

Last updated: 28/11/2023

Study Finalised

Administrative details

EU PAS number

EUPAS6366

Study ID

33224

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Netherlands
- [ ] United Kingdom

Study description

A non-interventional, post authorization safety study (PASS) to evaluate the safety of Kineret in the treatment of Cryopyrin Associated Periodic Syndromes (CAPS) in routine clinical care with focus on serious infections, malignancies, injection site reactions, allergic reactions and medication errors, including re-use of syringe

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

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

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Primary lead investigator

Marco Gattorno

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/10/2014

Actual: 01/10/2014

Study start date
Planned: 15/10/2014

Actual: 15/10/2014

Data analysis start date
Planned: 04/05/2015

Actual: 04/05/2015

Date of interim report, if expected
Planned: 30/06/2015

Actual: 30/06/2015

Date of final study report
Planned: 30/06/2020

Actual: 13/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Swedish Oprhan Biovitrum

Study protocol

PASS protocol Sobi.Anakin-201_v1_10JUN2014.pdf(345.53 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)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of the study is to evaluate the safety of Kineret treatment in CAPS patients in routine clinical care with focus on serious infections, malignancies, injection site reactions, allergic reactions and medication errors, including re-use of the syringe. The study is designed to address the effectiveness of the risk minimization measures for medication.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AC03) anakinra

anakinra

Medical condition to be studied

Cryopyrin associated periodic syndrome

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

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

20

Study design details

Outcomes

The primary endpoints of the study are: • Rate of serious infections • Rate of new malignancies • Rate of ISRs • Rate of allergic reactions • Rate of medication errors including re-use of syringe. Medication errors will be further

classified as infections of the injection site, re-use of syringe, over- or underdosing, or other medication errors. The secondary endpoints of the study are: • Kineret dose • Proportion of patients who discontinue Kineret treatment permanently (including reason for dicontinuation) • Proportion of patients who discontinue Kineret treatment temporarily (including reason for dicontinuation) • Proportion of patients who are transferred to another IL 1 blocking treatment

Data analysis plan

The presence of serious infections, new malignancies, ISRs, allergic reactions and medication errors will be presented as rates, calculated as the number of events divided by the total cumulative exposure to Kineret treatment in the study (patient years). 95% confidence intervals will be calculated for the rate of each of the five event types. In addition to the rate, the distribution of the severity, relationship to the Kineret treatment and seriousness will be presented. All enrolled patients will be included in the analysis. The analyses will be conducted primarily for the total study population. In addition, the subgroup of patients who are already using Kineret at baseline and the subgroup who initiate Kineret treatment at baseline will be analyzed separately.

Documents

Study results

Sobi.ANAKIN-201_CSR Synopsis.pdf(137.68 KB)

Data management

ENCePP Seal

Signed checklist for study protocols

Sobi.Anakin-201_Annex 2_ENCePP Checklist.pdf(465.87 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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