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

PURI
https://redirect.ema.europa.eu/resource/33063

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 institution 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
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~~06/10/2022~~

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

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 data collection

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

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