Severe Gout Registry (SGR)

First published: 08/04/2015

Last updated: 08/04/2015

Study Planned

Administrative details

EU PAS number

EUPAS9073

Study ID

9074

DARWIN EU® study

No

Study countries

Netherlands

Study description

The Dutch Society for Rheumatology (study group gout) has writtenand confirmed a guideline on good clinical use of canakinumab. In this guideline the registration of all gout patients prescribed canakinumab is advocated, including follow up on clinical outcomes, patient reported outcomes, safety and costs.

The objective of this study is to characterize the users, use and safety profile of canakinumab in the goutyarthritis population in the Netherlands and to mirror these results against a standard of care cohort of patients with frequent gout flares, not receiving canakinumab. The study will be a non-interventional, parallel-cohort, long-term safety study among gout patients experiencing frequent flares (≥ 3 yearly).

Study status

Planned

Research institutions and networks

Institutions

DREAM-RA

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Mart van de Laar

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/12/2014

Actual: 17/12/2014

Study start date
Planned: 01/01/2015

Date of final study report
Planned: 31/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To characterize the users, use and safety profile of canakinumab in the gouty arthritis population in the Netherlands and to mirror these results against a standard of care cohort of patients with frequent gout flares, not receiving canakinumab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AC08) canakinumab

canakinumab

Medical condition to be studied

Gouty arthritis

Population studied

Age groups

- 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

200

Study design details

Outcomes

To explore the overall efficacy and safety profile of canakinumabunder conditions of routine clinical care and provide data on the incidence rates of selected safety related outcomes in the population of frequently flaring gout flares and to mirror the results against a cohort of frequently flaring gout patients under standard care.

Data analysis plan

Descriptive statistics will be used to summarize all safety and effectiveness criteria. No formal hypothesis testing or statistical significance testing is planned. The primary analyses will include evaluating the frequency (proportions or rates and 95% CI) of serious infections, malignancies, hypersensitivity reactions and other selected events. Additional analyses will explore the frequency of markers of diseaseprogression, such as to be determined and the frequency of other SAEs considered potentially related to canakinumab or standard of care.

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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

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