A prospective, non-interventional study of the effectiveness, safety, and health related outcomes in patients with moderate to severe active rheumatoid arthritis receiving filgotinib (FILOSOPHY)

First published: 14/04/2021

Last updated: 05/09/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48323

EU PAS number

EUPAS39767

Study ID

48323

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Germany
- ☐ Italy
- ☐ Netherlands
- ☐ Spain
- ☐ United Kingdom

Study description

To describe the effectiveness, safety, and patient-reported outcomes in patients with moderate to severe active rheumatoid arthritis receiving filgotinib in real-world setting.

Study status

Ongoing

Research institutions and networks

Institutions

Alfasigma

☐ Italy

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Institution **Pharmaceutical company**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Monia Zignani

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 06/04/2021

Study start date
Actual: 11/05/2021

Date of final study report
Planned: 30/06/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alfasigma S.p.A

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

ClinicalTrials.gov Identifier: https://clinicaltrials.gov/ct2/show/NCT04871919

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 evaluate the treatment persistence rate at 24 months, defined as the rate of patients continuing to receive filgotinib 24 months from treatment initiation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

FILGOTINIB MALEATE

Medical condition to be studied

Rheumatoid 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

1304

Study design details

Outcomes

Treatment persistence rates at 24 months, Throughout the study: rates of AE and SAE during 24 months, patients' assessment of pain (Pain VAS), patients'

assessment of fatigue (FACIT-F score), patients' assessment of work productivity (WPAI-RA), disease activity (DAS28CRP and/or CDAI), medication adherence (CQR19 and CQR5), patients' assessment of Rheumatoid Arthritis Impact of Disease (RAID).

Data analysis plan

In general, for continuous variables, descriptive summary statistics will be provided including number of patients (N), mean, standard deviation (SD), minimum, median, and maximum, together with the number of missing values. Categorical variables will be summarized with counts and percentages, with missing values as separate category. Incidence rates and 95% confidence intervals (CIs) will be provided. Demographics and baseline characteristics will be summarized using descriptive statistics.

Data management

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