A Non-Interventional Prospective Study to Evaluate The Safety Of Long Term Use Of Grastofil In Patients With Severe Chronic Neutropenia Enrolled In The Severe Chronic Neutropenia International Registry (SCNIR)

First published: 02/06/2017

Last updated: 17/06/2020

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/35845

EU PAS number

EUPAS19412

Study ID

35845

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Serbia
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

Study to Evaluate The Safety Of Long Term Use Of Grastofil In Patients With Severe Chronic Neutropenia Enrolled In The Severe Chronic Neutropenia International Registry (SCNIR)Note: This study has been discontinued/cancelled based on the Grastofil (Filgrastim) updated Risk Management Plan (RMP) Version 6.0, dated 23-Jan-2020, which was approved by EMA through type-II variation (EMEA/H/C/002150/II/0030) on 11-Jun-2020.

Study status

Finalised

Research institutions and networks

Institutions

Hannover Medical School (MHH)

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Grzegorz Orlik

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/11/2012

Actual: 30/11/2012

Study start date

Planned: 01/02/2014

Actual: 01/02/2014

Date of final study report

Planned: 01/08/2024

Actual: 11/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Accord Healthcare S.L.U, Spain

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The objectives are 1) to monitor and assess long term safety of SCN patients treated with Grastofil (filgrastim) 2) to study the incidence and outcome of identified and potential risks such as osteoporosis, splenomegaly, cytogenetic abnormalities, myelodysplastic syndrome, and leukemia

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-Interventional Prospective Study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L03AA02) filgrastim

filgrastim

Medical condition to be studied

Neutropenia

Population studied

Short description of the study population

Patients With Severe Chronic Neutropenia Enrolled In The Severe Chronic Neutropenia International Registry (SCNIR)

Age groups

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)

Special population of interest

Pregnant women

Other

Special population of interest, other

Severe Chronic Neutropenia patients

Estimated number of subjects

500

Study design details

Data analysis plan

Data analysis and reports are generated twice yearly on Grastofil. The evaluation will focus on Patient Characteristics (age, gender, neutropenia diagnosis), Clinical Characteristics, Treatment, Adverse Events, Deaths, Pregnancy

Data management

Data sources

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