A multinational, multi-centre, prospective, non-interventional, post-authorisation safety study in healthy donors (HDs) exposed to Nivestim (biosimilar filgrastim) for haematopoietic stem cell (HSC) mobilisation (NEST)

First published: 11/07/2016

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Study Ongoing

Administrative details

EU PAS number

EUPAS14052

Study ID

34290

DARWIN EU® study

No

Study countries

- [ ] Greece
- [ ] Italy
- [ ] Portugal
- [ ] Spain

Study description

A non-interventional study in 100 healthy subjects due to receive or have recently (within 30 days) received Nivestim for mobilisation of HSCs in order to donate to HSC transplant patients. Healthy donors will be followed up for 5 years in order to review types and rates of adverse events of special interest, adverse drug reactions and new malignancies.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Banchero Querol Patricia

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 03/09/2015

Study start date
Planned: 30/07/2016

Actual: 30/08/2016

Data analysis start date
Planned: 07/02/2023

Date of interim report, if expected
Planned: 20/06/2018

Actual: 20/06/2018

Date of final study report
Planned: 18/04/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

PASS NEST_Healthy Donor Study Protocol_V 1 0 23 Oct 2015.pdf(1.01 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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:

To describe types and rates of adverse drug reactions (ADRs) and adverse events of special interest (AESI), especially new malignancies, in healthy donors (HDs) treated with Nivestim.

Study drug and medical condition

Name of medicine

NIVESTIM

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

100

Study design details

Outcomes

To describe the HD population exposed to Nivestim for HSC mobilisation. To describe effectiveness of Nivestim in HSC mobilisation in HDs.

Data analysis plan

Continuous variables will be described (distribution) by their mean, standard deviation, median, quartiles 1 and 3, extreme values (minimum and maximum) and the number of missing data. Categorical variables will be described (frequency) by their total and percentage and the number of missing data.

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