Post Authorization Rixubis Study (PARIXS)

First published: 04/06/2015

Last updated: 15/06/2016

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/13806

EU PAS number

EUPAS9847

Study ID

13806

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The study addresses the description of routine clinical practice with a new rFIX product (RIXUBIS) usingany therapeutic regimen administered to hemophilia B patients.This post-authorization, prospective, uncontrolled, observational, open-label, non-interventional,multicenter cohort study is designed to measure short and long-term outcomes in terms of effectiveness,safety, joint health, quality of life and economic outcomes in routine clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Hannover Medical School (MHH)

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

Multiple centres: 5 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andreas Tiede

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/01/2015

Actual: 20/01/2015

Study start date

Planned: 30/04/2015

Actual: 16/09/2015

Data analysis start date

Planned: 01/04/2022

Actual: 12/04/2016

Date of final study report

Planned: 30/06/2022

Actual: 10/06/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Baxalta

Study protocol

251401-protocol-2015mar20.pdf(413.33 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To assess hemostatic effectiveness in the prevention of bleeding events in subjects with hemophilia Breceiving rFIX (RIXUBIS) using any therapeutic regimen in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B02BD04) coagulation factor IX

coagulation factor IX

Medical condition to be studied

Haemophilia

Population studied

Short description of the study population

All patients with congenital hemophilia B receiving RIXUBIS in routine clinical practice.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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

Other

Special population of interest, other

Congenital haemophilia B patients

Estimated number of subjects

80

Study design details

Outcomes

To assess hemostatic effectiveness in the prevention of bleeding events in subjects with hemophilia Breceiving rFIX (RIXUBIS) using any therapeutic

regimen in routine clinical practice. To describe the safety and immunogenicity in subjects with hemophilia B receiving rFIX(RIXUBIS).To describe joint health outcomes in subjects receiving rFIX(RIXUBIS).Health-Related Quality of Life (HR-QoL) objectives:To describe acute and chronic pain associated with hemophilia, physical activity, hemophilia related comorbidity and healthcare recource use in subjects receiving rFIX (RIXUBIS)

Data analysis plan

Descriptive statistics of all endpoints will include specifically but not exclusively,arithmetic mean, medians, standard deviations, minimum, maximum, proportions,frequency counts, 25th and 75th percentiles, and 95% confidence intervals of select pointestimates. Figures will be prepared to illustrate the patterns of data over time whereappropriate. The number of subjects included in each analysis set will be reported.

Documents

Study results

251401-abstract-abbreviated-2016jun09.pdf(84.02 KB)

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