Non-Interventional Post-Marketing Safety Study on the Long-Term Safety of HYQVIA (Global)

First published: 14/11/2017

Last updated: 16/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21523

Study ID

49332

DARWIN EU® study

No

Study countries

☐ United States

Study description

The purpose of the proposed study is to acquire additional data (including the assessment of anti-rHuPH20 antibodies) on the long-term safety of HYQVIA and to assess the prescribed treatment regimens and product administration in routine clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Shire

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Institution

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

Study Contact Shire clinicaltransparency@shire.com

Study contact

clinicaltransparency@shire.com

Primary lead investigator

Study Contact Shire

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/03/2015

Actual: 17/09/2015

Study start date

Planned: 12/11/2015

Actual: 12/11/2015

Data analysis start date

Planned: 30/10/2021

Actual: 21/10/2021

Date of final study report

Planned: 16/05/2022

Actual: 16/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Baxalta, now part of Shire

Study protocol

161406-protocol-amend-2-2015sep17_redacted.pdf (1.26 MB)

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:

Disease /health condition

Human medicinal product

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 primary objective is to collect and assess additional safety data, in particular the occurrence of long-term changes in incidence and severity of related adverse events in patients treated with HYQVIA

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, uncontrolled, multi-center, open-label, post-marketing surveillance study

Study drug and medical condition

Medicinal product name

HYQVIA

Medical condition to be studied

Primary immunodeficiency syndrome

Population studied

Short description of the study population

The study involved adult subjects aged 16 years or older with primary immunodeficiency diseases (PIDD) who were prescribed or initiated treatment with HYQVIA to assess the safety and tolerability data under routine clinical conditions.

Inclusion criteria:

• Subject requires immunoglobulin treatment for PIDD

• Subject age is compatible with local package insert requirements (US ≥ 16, EU ≥ 18 years of age)

• Subject has been prescribed or has started treatment with HYQVIA

• Subject is willing and able to comply with the requirements of the protocol

Exclusion criteria:

• Subject has known hypersensitivity to any of the components of the medicinal product

• Subject has participated in an interventional clinical study involving a medicinal product or device within 30 days prior to enrollment or is scheduled to participate in an interventional clinical study involving a medical product or device during the course of this study

• Subject is a family member or employee of the investigator

Age groups

- 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

Immunocompromised

Pregnant women

Estimated number of subjects

250

Study design details

Outcomes

Incidence of all related serious adverse events (SAEs), Safety: - all SAEs and non-SAEs - immunologic AEs Treatment: 1. Regimen: - dose - infusion interval 2. Administration: - infusion volume - maximum infusion rate - mean infusion rate - duration of infusion - number of infusion sites Health-related quality of life and health resource use assessments

Data analysis plan

Statistical analyses and data displays will be mainly descriptive. Data from all enrolled subjects will be included in the analysis. If groups of sufficient sample size (such as: age groups, PIDD types) are available, confidence intervals may accompany the point estimates. All SAEs and non-serious AEs will be categorized according to MedDRA system organ class (SOC) and preferred term. Concomitant medications and non-drug therapies will be recorded and tabulated. Tables will be prepared to list for each SAE and non-serious AE the number of events and the number of subjects who experienced one or more

events.

Documents

Study results

161406-clinical-study-report-redact.pdf (716.12 KB)

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)

Drug 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