Non-Interventional Post-Authorization Safety Study on the Long-Term Safety of HyQvia in Subjects Treated with HyQvia (161302)

First published: 19/03/2014

Last updated: 22/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43051

EU PAS number

EUPAS5812

Study ID

43051

DARWIN EU® study

No

Study countries

- [ ] Czechia
- [ ] Denmark
- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands

Study description

This study is a non-interventional, prospective, uncontrolled, open-label, multi-center, post-authorization safety study to evaluate the long-term safety of HyQvia under clinical routine conditions. The HyQvia dosage regimen and treatment schedule will be chosen by the attending physician in accordance with routine clinical practice. There will be no required predefined visits, medical tests, laboratory tests and procedures beyond the treatment center's standard clinical practice during the course of the study, except for the assessment of antibodies to recombinant human hyaluronidase (rHuPH20) which was a request of the Committee for Medicinal Products for Human Use (CHMP).

Study status

Finalised

Research institutions and networks

Institutions

Shire

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Institution

Multiple centres: 25 centres are involved in the study

Contact details

Study institution contact

Study Contact Shire

Study contact

clinicaltransparency@shire.com

Primary lead investigator

Study Contact Shire

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/12/2013

Actual: 17/12/2013

Study start date
Planned: 30/07/2014

Actual: 17/07/2014

Data analysis start date
Actual: 14/02/2020

Date of final study report
Actual: 16/07/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Baxalta Innovations GmbH, now part of Shire

Study protocol

161302-protocol-original-redact.pdf(961.55 KB)

161302-protocol-amendment 3-redact.pdf(953.65 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

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

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

Long-term safety of HyQvia treatment in subjects receiving treatment with HyQvia

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, uncontrolled, multi-center, open-label, Post-Authorization Safety Study (PASS)

Study drug and medical condition

Name of medicine

HYQVIA

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

HYALURONIDASE (HUMAN RECOMBINANT)

Medical condition to be studied

Primary immunodeficiency syndrome

Chronic lymphocytic leukaemia

Plasma cell myeloma

Population studied

Short description of the study population

Adult patients (≥18 years) who were prescribed treatment with HyQvia were enrolled in the EEA.

Subjects who met ALL of the following criteria were eligible for this study:

1. Subject required IG treatment
2. Subject was ≥18 years old at the time of screening
3. Subject had been prescribed treatment with HyQvia prior to enrollment
4. Subject was willing and able to comply with the requirements of the protocol

Subjects who met ANY of the following criteria were not eligible for this study:

1. Subject had known hypersensitivity to any of the components of the medicinal product
2. Subject had participated in an interventional clinical study involving a medicinal product or device within 30 days prior to enrollment, or was scheduled to participate in an interventional clinical study involving a medicinal

product or device during the course of the study

3. Subject was a family member or employee of the investigator

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

111

Study design details

Outcomes

Incidence of all related serious adverse events (SAEs), Incidence of: - all SAEs and non-SAEs - immunologic AEs - temporally and/or causally associated systemic allergic AEs - new onset of other AEs that are potentially immunologically mediated - gastrointestinal symptoms - and titer of antibodies to rHuPH20, and other labs (if available) Dose Infusion interval 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.

Documents

Study results

161302-clinical-study-report-redact.pdf(747.19 KB)

Study report

161302 CSR Upload.pdf(39.44 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Source data comprised hospital records, medical records, clinical and office charts, laboratory notes, memoranda, subject diaries, home treatment records or evaluation checklists, outcomes reported by subjects, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, medical imaging data (eg, microfiches, photographic negatives, microfilm or magnetic media, X-rays), subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the study.

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