Pregnancy Registry to collect Long-Term Safety Data from Women treated with HyQvia

First published: 28/02/2014

Last updated: 16/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5798

Study ID

46485

DARWIN EU® study

No

Study countries

- ☐ Czechia
- ☐ Germany
- ☐ Poland
- ☐ Slovakia

United States

Study description

This study is a non-interventional, prospective, uncontrolled, two-arm, open-label, multicenter post-authorization pregnancy registry of women ever treated with HyQvia. Subjects who prior to the study received HyQvia and at enrollment receive a licensed human normal immunoglobulin other than HyQvia or an alternative treatment during the study will be assigned to Study Arm 1 (Alternative Product Arm), subjects in countries, where HyQvia treatment during pregnancy is not indicated, should be enrolled in this arm. Subjects who continue treatment with HyQvia during pregnancy will be followed in Study Arm 2 (HyQvia Arm). The registry is designed according to the CHMP Guideline on the exposure to medicinal products during pregnancy: Need for post authorisation data, and the U.S. Department of Health and Human Services Guidance for Industry: Establishing Pregnancy Exposure Registries. Female patients being treated with HyQvia will notify their treating physician (for example their immunologist) immediately of the pregnancy. Baxalta now part of Shire plans to have 1 coordinating center per country, with as many satellite sites as needed (sites where the pregnant women will be seen/treated).

Study status

Finalised

Research institutions and networks

Institutions

Shire

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 5 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: 27/06/2013

Actual: 27/06/2013

Study start date
Planned: 29/08/2014

Actual: 04/12/2015

Date of final study report
Planned: 28/02/2021

Actual: 10/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Baxalta Innovations GmbH, now part of Shire

Study protocol

161301_protocol amendment 3_22Oct2015_redacted.pdf(376.98 KB)

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

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To collect and assess clinical safety data regarding the possible effects of HyQvia on the course and outcome of the pregnancy, and on the growth and development of the fetus/infant exposed to HyQvia in utero.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, uncontrolled, two-arm, open-label, multicenter post-authorization study

Study drug and medical condition

Name of medicine

HYQVIA

Medical condition to be studied

Exposure during pregnancy

Population studied

Short description of the study population

Inclusion criteria

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

• For the expectant mother only: Subject became pregnant during or after treatment with HyQvia

• Subject/subject’s legally authorized representative was willing to sign informed consent form (ICF)

Exclusion criteria

There were no applicable exclusion criteria for this registry.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

20

Study design details

Outcomes

The incidence of all serious adverse events (SAEs), 1. Incidence of non-SAEs 2. Incidence of local/immunologic AEs 3. Development of anti-rHuPH20 antibodies 4. Complications of pregnancy 5. Fetal growth/development 6. Outcome of pregnancy 7. Neonatal assessment according to clinical practice 8. Status of the infant at birth 9. Growth measurement and charts for the infant 10. Development milestones determined by standard test methods

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Data analysis plan

Statistical analyses and data displays will be descriptive. Data from all enrolled subjects will be included in the analyses. Retrospective reports and prospective reports are clearly labeled. It will be considered to analyze them separately. All SAEs, non-serious AEs and other types of safety data will be categorized according to MedDRA system organ class (SOC) and preferred term, as far as possible. Tables will be prepared to list for each SAE, non-serious AE and other type of safety data, the number of events/data, and the number of subjects who experienced one or more events. Outcome measures regarding pregnancy loss, stillbirth, and congenital abnormalities, will be compared to published data for the region and, if known, for the specific patient population. Growth and development of the infant will be compared to growth parameters for the specific region, as appropriate, if available, or else to standard published charts.

Documents

Study results

161301-clinical-study-report-redact.pdf(883.54 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)

Other

Data sources (types), other

Source data for this study comprise the following: hospital records, medical records, clinical and office charts, laboratory notes, memoranda, evaluation checklists, outcomes reported by subjects, recorded data from automated instruments, subject files, and records kept 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