TAK-771-4004: Maternal and Infant Characteristics and Outcomes Following Exposure to HyQvia During Pregnancy: A Case Series Study Based on US Claims Data

First published: 16/03/2023

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106550

EU PAS number

EUPAS103800

Study ID

106550

DARWIN EU® study

No

Study countries

United States

Study description

The main aim of this study is to provide further information on the safety profile of HyQvia during pregnancy. This will be done by checking the characteristics of the mother and their babies. They will also be checked for any safety outcomes that will occur when exposed to HyQvia during pregnancy.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/02/2023

Actual: 24/02/2023

Study start date

Planned: 15/03/2023

Actual: 15/03/2023

Data analysis start date

Planned: 16/04/2023

Actual: 16/04/2023

Date of final study report

Planned: 30/06/2023

Actual: 16/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

TAK-771-4004-clinical-study-protocol-redact.pdf(1.21 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Primary objectives of study are to describe the maternal characteristics, patterns of HyQvia utilization and pregnancy outcomes in HyQvia-exposed pregnancies that would be identified within a US healthcare claims database of commercially insured individuals.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective case series

Study drug and medical condition

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

HUMAN NORMAL IMMUNOGLOBULIN

Medical condition to be studied

Pregnancy

Gestational hypertension

Congenital anomaly

Foetal malformation

Abortion spontaneous

Stillbirth

Population studied

Short description of the study population

The study population comprised of pregnant women exposed to HyQvia during pregnancy identified through MarketScan research database from 2014 to 2020 in the US.

Inclusion criteria:

• Pregnant human females ages 16-44

• Exposed to HyQvia in the etiologic window defined as 90 days prior to the LMP until the end of pregnancy.

Exclusion criteria:

• NA

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

7

Study design details

Outcomes

Number of Participants with Major Congenital Malformations in the Infant Number of Participants with Spontaneous Abortion Number of Participants with Stillbirth Number of Participants with Preterm Birth Number of Participants Being Small for Gestational Age Number of Participants With Admission to Neonatal Intensive Care Unit Number of Participants With Any Major Clinical Diagnosis/Procedure

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Data analysis plan

Description of complete claims profiles will be performed by reporting maternal and infant characteristics and outcomes after exposure to HyQvia during pregnancy. Separate narratives for each participant, will describe sociodemographic characteristics(age), medical history(comorbidities and concomitant medications), timing of HyQvia dispensations/administration, recorded indication, obstetric characteristics(e.g. infertility treatments, multiples), clinical diagnoses during pregnancy(e.g. infections), obstetric outcomes(e.g. preeclampsia), infant characteristics(sex), presence of pre-specify and other adverse pregnancy outcomes. Summary report will quantify frequency of pre-specified outcomes(e.g. out of xx pregnancies exposed, yy ended in livebirths). Given small numbers, no absolute risks(with 95% confidence intervals) will be calculated. Since there is no reference group, no measures of association(e.g. relative risks) will be estimated. No causal inference will be attempted.

Documents

Study results

TAK-771-4004-clinical-study-report-redact.pdf(751.29 KB)

Data management

Data sources

Data source(s), other

MarketScan United States

Data sources (types)

Administrative healthcare records (e.g., claims)

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