Postmarketing commitment safety study of HZ/su to evaluate pregnancy exposures and outcomes in immunodeficient or immunosuppressed women between 18 and 49 years of age (EPI-ZOSTER-039 VS US DB 214420)

First published: 31/03/2023

Last updated: 11/02/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105603

EU PAS number

EUPAS104070

Study ID

105603

DARWIN EU® study

No

Study countries

☐ United States

Study description

The study will examine the risk of selected infant and pregnancy outcomes in immunodeficient or immunosuppressed women exposed to herpes zoster subunit vaccine (HZ/su) during pregnancy.

Study status

Ongoing

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Harvard Pilgrim Health Care Institute

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Call Center EU GSK Clinical Trials

Study contact

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Primary lead investigator

Call Center EU GSK Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/11/2022

Study start date

Planned: 03/04/2023

Actual: 09/05/2022

Date of final study report

Planned: 30/04/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK

Study protocol

Protocol_Amendment_2_Anonymized.pdf(1.03 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 type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To evaluate the prevalence of major congenital malformations (MCMs) among live births from women with immunocompromised (IC) conditions exposed to HZ/su compared to those not exposed to HZ/su during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

SHINGRIX

Medical condition to be studied

Herpes zoster

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Immunocompromised

Pregnant women

Estimated number of subjects

2844

Study design details

Outcomes

Major congenital malformations (MCMs) among live births from women with immunocompromised (IC) conditions exposed to HZ/su compared to those not exposed to HZ/su during pregnancy.
Additional infant/birth outcomes among live births in women with IC conditions exposed to HZ/su versus those not exposed to HZ/su during pregnancy.
Pregnancy outcomes and pregnancy complications among livebirth and non-livebirth pregnancies in women with IC conditions exposed to HZ/su versus those not exposed to HZ/su during pregnancy.

Data analysis plan

Annual descriptive analyses to estimate the counts of HZ/su exposed pregnancies among women with IC conditions will be performed.
Data from the first two years will be used to determine the feasibility of a full-scale cohort study.
If the feasibility assessment identifies that the number of HZ/su-exposed pregnancies is equal to or above the target number of exposed pregnancies, a subsequent cohort study will be conducted.
The prevalence of MCMs and additional infant/birth outcomes and their associated 95% CIs will be calculated among women with IC conditions who were exposed to HZ/su during pregnancy versus the corresponding matched women who were not exposed to HZ/su during pregnancy.
The prevalence of the pregnancy outcomes and pregnancy complications and

their 95% CIs will be calculated between the two groups of women.
All analyses will be stratified by stage of pregnancy (pre-pregnancy, first trimester, second trimester, third trimester).

Data management

Data sources

Data source(s), other

CVS Health Clinical Trial Services United States, HealthCore, Inc United States, Optum 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