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: 05/09/2025

Study | Ongoing

Administrative details

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

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution Outdated Other ENCePP partner

Harvard Pilgrim Health Care Institute

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Carelon Research, United States

CVS Health Clinical Trial Services, United States

Contact details

Study institution contact

Call Center EU GSK Clinical Trials RD.CTT-globalmailbox@gsk.com

Study contact

RD.CTT-globalmailbox@gsk.com

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: 09/05/2022

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)

Protocol Amendment 3 Anonymised 17 Apr 2025.pdf (1.27 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 topic:

Other

Study topic, other:

Safety study

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

Medicinal product name

SHINGRIX

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

HERPES ZOSTER VACCINE (RECOMBINANT, ADJUVANTED)

Anatomical Therapeutic Chemical (ATC) code

(J07BK03) zoster, purified antigen

zoster, purified antigen

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

MCMs among live births from women with 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 and unexposed 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 1/3 of the target number of exposed pregnancies for the cohort study (n=711 for cohort study; n=237 for feasibility assessment), 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

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 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