Bexsero® pregnancy registry: an observational study of the safety of Bexsero® exposure in pregnant women and their offspring

First published: 25/01/2016

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12183

Study ID

36639

DARWIN EU® study

No

Study countries

☐ United States

Study description

4CMenB was approved by the European Medicines Agency (EMA) in January 2013 and is indicated for active immunisation of individuals from 2 months of age and older against invasive meningococcal disease caused by Neisseria meningitidis group B. 4CMenB can be considered for use during pregnancy where there is a clear risk of exposure to meningococcal infection and sometimes, inadvertent exposure during pregnancy may also occur - before the woman knows she is pregnant, for example. The objective of this study is to evaluate the safety of 4CMenB during pregnancy and to help us learn more about the health of women who have been vaccinated with 4CMenB within 30 days prior to their last menstrual period (LMP) or at any time during pregnancy, and the health of their infants. The study will be conducted (with EMA approval) in the US. Pregnant women within the US who received at least 1 dose 4CMenB vaccine within 30 days prior to their last menstrual period or at any time during pregnancy are eligible to participate. A woman may self-enroll in the registry by calling the pregnancy registry telephone number directly or their healthcare provider (HCP) can, with their consent, enroll them on their behalf. Alternatively HCPs may report anonymous data on pregnancy exposures and outcomes occurring within their network/health maintenance organization (HMO). The health of the woman and her infant will be followed up until the end of the pregnancy

---

Study status

Finalised

Research institutions and networks

Institutions

Pharmaceutical Product Development (PPD)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Call Center EU Clinical Trials

Vx.publicdisclosureglobal@gsk.com

Study contact

Vx.publicdisclosureglobal@gsk.com

Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/11/2015

Study start date

Actual: 31/01/2016

Date of final study report

Actual: 02/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Vaccines, now a GSK company

Study protocol

V72_82OB-08_Other_(Specify)-Redacted_Protocol_for_ENCePP-v1-2015-11-20-77194739.pdf(1 MB)

gsk-205533-protocol-redact.pdf(791.72 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:

Other

If ‘other’, further details on the scope of the study

Post-authorization safety study

Data collection methods:

Primary data collection

Main study objective:

The objective of the 4CMenB Pregnancy Registry is to evaluate pregnancy outcomes among women immunized with the 4CMenB vaccine within 30 days prior to LMP or at any time during pregnancy.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Pregnancy Registry, Prospective, observational study

Study drug and medical condition

Name of medicine

BEXSERO

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

RECOMBINANT NEISSERIA MENINGITIDIS GROUP B NHBA FUSION PROTEIN
RECOMBINANT NEISSERIA MENINGITIDIS GROUP B NADA PROTEIN
RECOMBINANT NEISSERIA MENINGITIDIS GROUP B FHBP FUSION PROTEIN PRODUCED IN E. COLI CELLS BY RECOMBINANT DNA TECHNOLOGY ADSORBED ON ALUMINIUM HYDROXIDE
OUTER MEMBRANE VESICLES FROM NEISSERIA MENINGITIDIS GROUP B (STRAIN NZ 98/254)

Anatomical Therapeutic Chemical (ATC) code

(J07AH09) meningococcus B, multicomponent vaccine
meningococcus B, multicomponent vaccine

Medical condition to be studied

Pregnancy

Population studied

Short description of the study population

The study population will include pregnant women within the US who received at least 1 dose of Bexsero® vaccine (confirmed or possible exposure) within 30 days prior to LMP or at any time during pregnancy. Bexsero® should be used during pregnancy only if clearly needed, but inadvertent exposure during pregnancy might be expected because the age group targeted for the vaccine includes young women of reproductive potential.
The minimum criteria required for enrollment into the registry are as follows:

1. Sufficient evidence to confirm that exposure to a serogroup B meningococcal vaccine (confirmed or possible Bexsero® vaccination) occurred within 30 days prior to LMP or at any time during pregnancy
2. Sufficient information to determine whether the pregnancy is prospectively or retrospectively registered (i.e., whether the outcome of pregnancy was known at the time of first contact with the registry)
3. Date the pregnancy exposure is registered
4. Full reporter (i.e., HCP) contact information to allow for follow-up (name, address, etc.)

Age groups

Preterm newborn infants (0 – 27 days)

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

1

Study design details

Outcomes

The primary outcomes of interest include major congenital malformation (MCM), preterm birth, and low birth weight (LBW). Other pregnancy outcomes including stillbirth, spontaneous abortion (SAB), induced abortion (IAB), ectopic pregnancy, molar pregnancy.

Data analysis plan

A SAP will be completed before the study is started.Demographic and baseline characteristics will be summarized with simple descriptive statistics and data listings. The overall prevalence of MCM will be reported as well as the prevalence of preterm births and low birth weight infants. These prevalence estimates in exposed subjects will be compared with those of the Centres for Disease Control's (CDC) National Vital Statistics System (NVSS).

Documents

Study results

gsk-205533-clinical-study-report-redact.pdf(458.77 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)

Disease registry

Other

Data sources (types), other

The pregnant woman and appropriate members of her health care team could serve as data reporters to the registry. The registry was strictly observational, and only data noted as part of routine care would be collected.

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