HEPLISAV-B® Pregnancy Registry: an observational study on the safety of HEPLISAV-B exposure in pregnant women and their offspring (DV2-HBV-27)

First published: 03/02/2023

Last updated: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50523

EU PAS number

EUPAS50522

Study ID

50523

DARWIN EU® study

No

Study countries

United States

Study description

The objective of the HEPLISAV-B® Pregnancy Registry is to evaluate pregnancy outcomes among women who received a dose of the HEPLISAV-B vaccine within 28 days prior to conception or at any time during pregnancy. This registry is primarily descriptive and designed to detect potential safety signals rather than test hypotheses. This study is strictly observational. Administration of HEPLISAV-B, the schedule of office visits and all treatment regimens will be determined by the treating health care provider in the context of routine clinical care.

Study status

Ongoing

Research institutions and networks

Institutions

Dynavax Technologies

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Robert S. Janssen

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/12/2017

Study start date
Actual: 11/06/2021

Data analysis start date
Planned: 01/12/2023

Date of final study report
Planned: 31/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Dynavax Technologies Corporation

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

The objective of the HEPLISAV-B® Pregnancy Registry is to evaluate pregnancy outcomes among women who received a dose of the HEPLISAV-B vaccine within 28 days prior to conception or at any time during pregnancy. This registry is

primarily descriptive and designed to detect potential safety signals rather than test hypotheses.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective observational study of pregnant women who received dose of HEPLISAV-B vaccine within 28 days prior to conception or any time during pregnancy. Registry will collect data routinely documented in medical records in the course of usual care

Study drug and medical condition

Name of medicine

HEPLISAV B

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

HEPATITIS B SURFACE ANTIGEN

Anatomical Therapeutic Chemical (ATC) code

(J07BC01) hepatitis B, purified antigen

hepatitis B, purified antigen

Medical condition to be studied

Hepatitis B virus test

Congenital anomaly

Additional medical condition(s)

Major congenital malformations (MCMs) is defined as any major structural or chromosomal defect or combination of two or more conditional defects in live-born infants, stillbirths, or fetal losses of any gestational age (including outcomes prior to 20 weeks' gestation or birth weight <,500 g).

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

300

Study design details

Outcomes

Rate of Major Congenital Malformations in Live-Born Infants Time Frame: Live-born infants will be followed to 12 months of age, Rate of Still Births, Pre-Term, or Fetal Loss (Including Spontaneous Abortion) of any Gestational Age Time Frame: Follow-up will end at the time of pregnancy outcome up to 9 months, Preterm birth (an infant born at gestational age < 37 weeks), Stillbirth (a fetal death occurring at 20 weeks' gestation or greater, or, if gestational age is

unknown, a fetus weighing 500 g or more), Spontaneous abortion (SAB) (fetal death or expulsion of products of conception prior to 20 weeks’ gestation. Terminology may include missed abortion, incomplete abortion, and inevitable abortion)

Data analysis plan

This study is observational, and epidemiological methods will be employed for data collection and analyses. In general, statistical analyses will be descriptive in nature and will be conducted by data analysts in accordance with the study objectives, statistical analysis plan (SAP), table/listing shells referenced herein, and applicable guidelines. No formal comparisons are planned, and no hypotheses will be formally tested. For each continuous variable, the number of observations, median, mean, standard deviation, minimum, and maximum will be provided. For each categorical variable, the frequency and percentage in each category will be provided. Results will be rounded to 1 decimal place, therefore, percentages may not always add up to 100. The use of statistical tests will be limited (given the descriptive nature of the study), favoring instead 95% confidence intervals to reflect uncertainty. Data will be summarized in tables and listings as appropriate.

Data management

Data sources

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

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