The MenQuadfi™ Pregnancy Registry: A surveillance registry to assess the safety of MenQuadfi™ among exposed pregnant women and their offspring (MEQ00070)

First published: 26/03/2021

Last updated: 21/02/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS38093

Study ID

38094

DARWIN EU® study

No

Study countries

☐ United States

Study description

The primary objective of the pregnancy registry will be to assess maternal, obstetrical, pregnancy, and neonatal and infant outcomes among women vaccinated with MenQuadfi™ during pregnancy or in the 30 days preceding their last menstrual period (LMP).

Study status

Ongoing

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team Contact-Us@sanofi.com

Study contact

Contact-Us@sanofi.com

Primary lead investigator

Trial Transparency Team Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 22/07/2020

Actual: 22/07/2020

Study start date
Planned: 05/04/2021

Actual: 05/03/2021

Date of final study report
Planned: 01/02/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

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)

Other study registration identification numbers and links

MEQ00070

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

To assess maternal, obstetrical, pregnancy, neonatal and infant among women vaccinated with MenQuadfi™ during their pregnancy or within 30 days prior to

their last menstrual period (LMP).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

An observational, post-marketing, passive surveillance program to collect information on women and their offspring exposed to MenQuadfi™ during pregnancy. The reporting will be voluntary from women or their health care provider.

Study drug and medical condition

Name of medicine

MENQUADFI

Anatomical Therapeutic Chemical (ATC) code

(J07AH08) meningococcus A,C,Y,W-135, tetravalent purified polysaccharides antigen conjugated

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Medical condition to be studied

Exposure during pregnancy

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Study design details

Outcomes

The outcomes of interest will consist of any reported adverse event, including both symptoms, diagnoses, and normal outcomes following vaccination of a pregnant woman. Primary outcomes are classified as “maternal” if they impact maternal health but are independent of the pregnancy, “obstetrical” if they are related directly to the pregnancy, “pregnancy” if they are related to labor and delivery. Secondary outcomes will be any reported adverse event including both symptoms, diagnoses, and normal outcomes following vaccination of a pregnant woman, that will be classified as “neonatal” if related to the infant and assessed immediately after birth or within the first 28 days of life (e.g. congenital anomalies), and “infant” for those occurring / diagnosed between days 29 and 365 post-birth.

Data analysis plan

The population of women exposed to MenQuadfi during pregnancy and their offspring will be reported using appropriate descriptive statistics. To assess the safety of MenQuadfi exposure during pregnancy, frequencies of SAEs observed among women enrolled in the pregnancy registry and their offspring and the

corresponding 95% CIs will be compared qualitatively to those expected in the general US population of pregnant women prior to the availability of MenQuadfi.

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)

Other

Pregnancy registry

Spontaneous reports of suspected adverse drug reactions

Data sources (types), other

Passive surveillance pregnancy registry

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