A Pregnancy Registry to Evaluate the Safety of Dengue Vaccine among Inadvertently Exposed Pregnant Women and their Offsprings

First published: 25/06/2021

Last updated: 18/12/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46441

EU PAS number

EUPAS31210

Study ID

46441

DARWIN EU® study

No

Study countries

Brazil

Study description

This will be a Pregnancy Registry Study that utilizes active identification and enrollment of a cohort of pregnant women of any age and their offsprings who were inadvertently exposed to CYD tetravalent dengue vaccine (CYD-TDV) anytime during the pregnancy or in the 30 days preceding their last menstrual period (i.e., periconceptional period). Data collection will utilize a hybrid approach comprised of the use of structured interviews supplemented by medical records review (primary data sources), and the use of health and mortality databases (secondary data sources).

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team

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: 07/10/2019

Actual: 26/05/2020

Study start date

Planned: 22/01/2022

Actual: 11/03/2022

Date of final study report

Planned: 21/08/2023

Actual: 08/07/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

rdct-dng16-protocol.pdf(1.88 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

DNG16,U1111-1212-3443,NCT04023708

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To evaluate the safety of CYD-TDV in pregnant women and their offsprings inadvertently exposed during pregnancy or up to 30 days preceding their last menstrual period (LMP) with regards to maternal, pregnancy, birth, neonatal and infant outcomes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

DENGVAXIA

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)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

214

Study design details

Outcomes

The primary study endpoints will include all serious and non-serious maternal, pregnancy related, birth outcomes, neonatal and infant events occurring anytime between cohort entry and the end of follow-up for each event. Participant unique anonymized identifier, relevant maternal baseline characteristics, maternal data (type of conception, date of LMP, and estimated date of delivery), characteristics of prenatal care, characteristics of CYD-TDV exposure (dates doses administered, number of doses, dose intervals, and timing of pregnancy exposure), offspring data (sex, length, weight, and breastfeeding history).

Data analysis plan

To assess the safety of CYD-TDV exposure during pregnancy, descriptive analyses will be undertaken to summarize the maternal, pregnancy, birth,

neonatal and infant outcome data using frequencies expressed as absolute risk estimates with corresponding 95% CIs, and these data will be compared background incidence rates for the age-matched population in Paraná prior to the availability of CYD-TDV (i.e. unvaccinated comparator population). In addition, analyses will be stratified by reporting status (prospective vs. retrospective), as well as by trimester of exposure, with an additional stratum for periconceptional exposure. Reports of multiple CYD-TDV exposures during a pregnancy will be classified according to the earliest pregnancy exposure. Descriptive analyses will also be undertaken to characterize pregnancy exposure with regards to number of doses received, dose intervals and trimester of exposure, as well as the population of pregnant women inadvertently exposed to CYD-TDV.

Documents

Study report

rdct-dng16-csr-synopsis.pdf(232.7 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Spontaneous reporting system, Prospective patient-based data collection, Exposure registry, Mortality database

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