A Prospective Observational Safety Study on Pregnancy Outcomes in Women Immunized With Seasonal Cell Culture Influenza Trivalent (TIVc) or Quadrivalent (QIVc) Vaccine During Pregnancy (Flucelvax (TIVc or QIVc) Pregnancy Registry)

First published: 20/08/2019

Last updated: 17/09/2025

Study Finalised

Administrative details

EU PAS number

EUPAS29472

Study ID

41943

DARWIN EU® study

No

Study countries

United States

Study description

The study is a population based prospective cohort study designed to collect data on pregnancy outcomes and events of interest among women immunized with the seasonal cell culture trivalent influenza virus (TIVc) or the seasonal cell culture quadrivalent influenza virus (QIVc) vaccine during pregnancy. The study population will include pregnant women within the US who were immunized with the TIVc or QIVc vaccine as part of routine care at any time during pregnancy. Eligible pregnant women may self-enroll or voluntarily be enrolled by their health care provider (HCP). Women under 18 can be included in the study as long as parental consent can be obtained. De-identified data on minors will be accepted into the study if permitted by laws and regulations.

Study status

Finalised

Research institutions and networks

Institutions

Syneos Health

United Kingdom

First published: 23/04/2015

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

UWCR Winston-Salem, NC

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Head Epidemiology Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/05/2017

Actual: 23/05/2017

Study start date

Planned: 01/09/2017

Actual: 01/09/2017

Data analysis start date

Planned: 31/08/2020

Actual: 03/11/2020

Date of final study report
Planned: 30/04/2021

Actual: 01/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Seqirus Inc.

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

V130_11OB, NCT03438487

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

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 evaluate pregnancy outcomes as well as events of interest of major congenital malformations, preterm birth and low birth weight among women immunized as part of routine care with the seasonal cell culture influenza trivalent (TIVc) or quadrivalent (QIVc) vaccine during pregnancy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

FLUCELVAX

Medical condition to be studied

Influenza immunisation

Population studied

Short description of the study population

The study population will include pregnant women within the US who were immunized with the TIVc or QIVc vaccine as part of routine care at any time during pregnancy. Eligible pregnant women may self-enroll or voluntarily be enrolled by their health care provider (HCP). Women under 18 can be included in the study as long as parental consent can be obtained.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

693

Study design details

Outcomes

Number of cases for pregnancy outcomes will be reported as one of the following: live birth, stillbirth, spontaneous abortion and elective termination. Number of cases with major congenital malformations, events of preterm birth,

and low birth weight among women immunized as part of routine care with the seasonal TIVc or QIVc vaccine during pregnancy.

Data analysis plan

This study is descriptive. Data analysis will be performed for both products combined as well as per product separately, if applicable. Overall and stratum-specific prevalence estimates will be calculated for pregnancy outcomes and events of interest. Associations between exposure and pregnancy outcomes or events of interest, will be evaluated for confounding and effect modification.

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

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