Zanamivir 10mg/ml solution for infusion pregnancy registry: an observational study of the safety of zanamivir 10mg/ml solution for infusion exposure in pregnant women with complicated influenza and their offspring (208140)

First published: 29/01/2020

Last updated: 30/09/2024

Study Finalised

Administrative details

EU PAS number

EUPAS33189

Study ID

49381

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The study was cancelled before active. To evaluate pregnancy outcomes among women with complicated influenza exposed to zanamivir 10mg/mL solution for infusion at any time during pregnancy including: 1) maternal death, 2) pregnancy outcomes including spontaneous losses in clinically recognized pregnancies, induced abortions, stillbirths and live births and 3) birth outcomes including low birth weight, small for gestational age, prematurity, congenital malformations and neonatal death.

Study status

Finalised

Research institutions and networks

Institutions

OXON Epidemiology

Spain

United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution **Laboratory/Research/Testing facility** **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/07/2019

Actual: 29/07/2019

Study start date

Planned: 20/11/2020

Actual: 20/11/2020

Date of final study report

Planned: 19/06/2024

Actual: 19/06/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-208140-protocol-redact.pdf(1.47 MB)

gsk-208140-protocol-am1-redact.pdf(298.48 KB)

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)

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 pregnancy outcomes among women with complicated influenza exposed to zanamivir 10mg/mL solution for infusion at any time during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

DECTOVA

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

ZANAMIVIR

Anatomical Therapeutic Chemical (ATC) code

(J05AH01) zanamivir

zanamivir

Medical condition to be studied

Influenza

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)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

100

Study design details

Outcomes

- Number of Maternal deaths
- Number of pregnant women with Live birth
- Number of participants with Spontaneous abortion
- Number of participants with stillbirth
- Number of participants with Induced Abortion
- Number of premature births
- Number of small gestational age infants
- Number of low birth weight (LBW) infants
- Number of neonatal deaths
- Number of births with major congenital malformation

Data analysis plan

The registry is primarily descriptive aiming to determine a signal for substantial increase in risk. Therefore, comparisons will be descriptive. Primary

comparisons will be against external comparators reflecting population-based surveillance of pregnancy outcomes and literature based disease based cohorts. If it is feasible, descriptive comparisons between the registry and an appropriate internal comparator will be examined.

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

Exposure 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