

# 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

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### Study ID

49381

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### DARWIN EU® study

No

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### Study countries

## 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.

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## 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](mailto: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

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### **Study start date**

Planned: 20/11/2020

Actual: 20/11/2020

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### **Date of final study report**

Planned: 19/06/2024

Actual: 19/06/2024

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## 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

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### **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

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#### **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

**Medicinal product name**

DECTOVA

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

ZANAMIVIR

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**Anatomical Therapeutic Chemical (ATC) code**

(J05AH01) zanamivir

zanamivir

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**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)
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## **Special population of interest**

Pregnant women

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## **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
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## **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

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#### Data sources (types), other

Exposure registry

### Use of a Common Data Model (CDM)

#### CDM mapping

No

### Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No