Assessing the safety of oseltamivir exposure in pregnant women

First published: 19/04/2016

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12875

Study ID

21489

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

This study will assess the association of exposure to oseltamivir during pregnancy and maternal outcomes, pregnancy outcomes and birth defects in the offspring.The research question will be addressed by conducting a cohort

study (part 1), investigating all aspects of the research question.In a second part, a nested case-control study, the association between oseltamivir and malformations will further be investigated.

Study status

Finalised

Research institutions and networks

Institutions

F. Hoffmann-La Roche

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Barry Clinch

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/10/2014

Study start date
Planned: 01/06/2016

Actual: 01/03/2016

Date of final study report
Planned: 28/02/2017

Actual: 20/01/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

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

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To assess the association of exposure to oseltamivir during pregnancy and birth defects in the offspring, particularly those of the circulatory system.

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

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

OSELTAMIVIR

Medical condition to be studied

Influenza

Population studied

Short description of the study population

Pregnant women in Denmark whose pregnancies were starting and ending between 01 January 2002 and 31 December 2013 and were prescribed oseltamivir during pregnancy.

Age groups

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

0

Study design details

Outcomes

-Babies with birth defects: EUROCAT classification, diagnosed up to one year postnatal among live born babies -Pregnancy outcomes: Live birth, preterm delivery, ’small for gestational age’ Apgar score at 5 minutes, stillbirth, induced and spontaneous abortions -Maternal outcomes: treatment-emergent hospital diagnoses in the mother occurring within 28 days of receipt of oseltamivir

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Data analysis plan

Cohort Study (Part 1)Matched and non-matched comparisons between exposed and unexposed pregnancies for all outcomes of interest will be performed. Exposed and unexposed cohorts will be characterised descriptively for the distribution of covariates (only before matching) and potential confounders before and after matching.Case-control Study (Part 2)Conditional multivariate logistic regression for matched case-controls will be used to estimate odds ratios for the association between first trimester exposure to oseltamivir and malformations. Distributions of potential confounders among the exposed and unexposed will be presented. The calculation will be conducted for the category of overall malformations and malformations of special interest, such as those of the circulatory system.

Documents

Study results

Final CSR, Study BV29684, Synopsis.pdf(83.56 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Linked population-based registries in Denmark

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

Unknown