Safety of influenza AH1N1 pandemic vaccination during pregnancy: a comparative study using the EFEMERIS database

First published: 05/12/2013

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5359

Study ID

16879

DARWIN EU® study

No

Study countries

☐ France

Study description

Pregnant women are at increased risk of severe disease and death due to influenza infection. During the influenza AH1N1 pandemic in 2009–2010, recommendations in France were to vaccinate pregnant women during the second and third trimester preferably with a non-adjuvant vaccine. However, few data are available concerning this drug in pregnant women. The aim of the study was to compare birth outcomes between exposed and unexposed women to influenza AH1N1 vaccine during pregnancy. This observational cohort study compared 2 groups of exposed and unexposed pregnant women in EFEMERIS. EFEMERIS is a database including prescribed and dispensed reimbursed drugs during pregnancy (data from Caisse Primaire d'Assurance Maladie of Haute-Garonne) and outcomes (data from Maternal and Infant Protection Service and from Antenatal diagnosis Centre). Women who delivered from October 21th 2009 to November 30th 2010 in Haute-Garonne and were registered in the French Health Insurance Service have been included.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse

France

First published: 31/03/2022

Last updated: 01/07/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Contact details

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Study contact

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Primary lead investigator

Christine Damase-Michel

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/04/2012

Study start date

Actual: 01/05/2012

Data analysis start date

Actual: 01/05/2012

Date of final study report

Actual: 01/06/2013

Sources of funding

- Other

More details on funding

Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM), CNAMTS, the Clinical Research Hospital Program

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective was to evaluate the risk of adverse pregnancy outcomes following A/H1N1 vaccination in pregnant women.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

INFLUENZA A (H1N1) 2009 MONOVALENT VACCINE

Population studied

Short description of the study population

Pregnant women in EFEMERIS database who were either exposed or unexposed to influenza AH1N1 vaccine and who delivered from October 21th 2009 to November 30th 2010 in Haute-Garonne.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Estimated number of subjects

5000

Study design details

Outcomes

all-cause pregnancy loss, preterm delivery, small for gestational age (SGA) and neonatal pathology

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Data analysis plan

The study compared vaccinated and non-vaccinated pregnant women. Two non-vaccinated women were individually matched to each vaccinated women by month and year of pregnancy onset. Multivariable conditional logistic regression and multivariable cox proportional hazards regression were used to evaluate associations between each outcome (all-cause pregnancy loss, preterm delivery, small for gestational age (SGA) and neonatal pathology) and A/H1N1 vaccination during pregnancy.

Documents

Study publications

Beau AB, Hurault-Delarue C, Vidal S, Guitard C, Vayssiere C, Petiot D, Montastr…

Data management

Data sources

Data source(s)

EFEMERIS

Data sources (types)

Administrative healthcare records (e.g., claims)

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

Unknown