A/H1N1 pandemic vaccines and pregnancy outcomes

First published: 17/11/2010

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/5304

EU PAS number

EUPAS1705

Study ID

5304

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Finland
- ☐ Germany

- [ ] Italy
- [ ] Netherlands
- [ ] Sweden
- [ ] United Kingdom

Study description

1) identification of relevant research centres, organisations and agencies active in the evaluation and safety of A/H1N1 vaccine safety in pregnant women,2) organise and coordinate an exchange of information between these centres, organisations and agencies with the aim to conduct a meta analysis of study results where appropriate,3) In collaboration with all stakeholders, produce a proposal for a long-term collaboration between research centres active in the field of drugs and pregnancy outcomes, including interaction with ENCePP, this deliverable will involve extending the profile of centres included in the inventory mentioned under 1)

Study status

Finalised

Research institutions and networks

Institutions

University of Bath

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Electronic Health Records (EHR) Research Group, London School of Hygiene & Tropical Medicine (LSHTM)

United Kingdom

First published: 19/04/2010

Last updated: 30/10/2024

Institution | Educational Institution | ENCePP partner

Pharmacy & Pharmacology, University of Bath

United Kingdom

First published: 30/04/2010

Last updated: 08/04/2019

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

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Corinne de Vries

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 19/10/2010

Actual: 19/10/2010

Study start date
Planned: 19/10/2010

Actual: 26/10/2010

Data analysis start date
Planned: 30/11/2012

Date of interim report, if expected
Planned: 19/07/2011

Date of final study report
Planned: 30/06/2013

Actual: 31/01/2013

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Other

If ‘other’, further details on the scope of the study

Setting up a network for drug safety in pregnancy evaluation

Data collection methods:

Secondary use of data

Main study objective:

to identify all studies of H1N1 vaccine safety in pregnancy, to conduct meta analyses of the studies identified as appropriate, and to set up a network for

evaluation of drug safety in pregnancy.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Name of medicine, other

INFLUENZA VIRUS, TYPE A, H1N1 7.0 LOG 10 FFU (FLUORESCENT FOCUS UNITS) PER DOSE

Medical condition to be studied

Exposure during pregnancy

Population studied

Short description of the study population

Pregnant women

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

2

Study design details

Outcomes

1) inventory of studies, 2) quantification of adverse pregnancy outcomes, 3) establishment of network

Data analysis plan

We will establish whether it is appropriate to pool the data and to analyse the pooled data where appropriate. Heterogeneity in study results between participating centres will be identified, evaluated, and where necessary we will go back to the data suppliers for any additional verification exercises required. When appropriate, a pooled analysis will be carried out.

Documents

Study results

EMA H1N1 Jan 2013_EMA.pdf(186.87 KB)

Study report

Charlton_DeVries_Final report data sources for medicines in pregnancy research.pdf(312.26 KB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Drug registry

Other

Data sources (types), other

Prospective patient-based data collection, Case-control surveillance database

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