PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Safety of the new H1N1 influenza vaccine in pregnancy

Trial Acronym

[---]*

URL of the trial

http://www.embryotox.de/aktuelles.html

Brief Summary in Lay Language

The new H1N1 influenza may pose an increased risk of severe illness in pregnant women, hence the Strategic Advisory Group of Experts on Immunization of the World Health Organization recommends vaccination in pregnant women. In Germany, the vaccine commission of the Robert Koch-Institut recommends that pregnant women be vaccinated preferably from the 2nd trimester and use non-adjuvanted vaccines. However, data on the possible adverse effects of the vaccine on the foetus are sparse. The aim of this study is therefore to evaluate the safety of the new H1N1 vaccine in pregnancy and to evaluate the possible adverse effects on the course of pregnancy or the newborn.

Brief Summary in Scientific Language

The new H1N1 influenza may pose an increased risk of severe illness in pregnant women, maybe due to the physiological and immunological changes happening during pregnancy. Hence the Strategic Advisory Group of Experts on Immunization of the World Health Organization recommends vaccination in pregnant women. In Germany, the vaccine commission of the Robert Koch-Institut recommends that pregnant women be vaccinated preferably from the 2nd trimester and use non-adjuvanted vaccines. Possible teratogenic effects have only been studied for the seasonal influenza vaccine, and there was no increased risk found so far, though there is not enough data to draw a definitive conclusion. The FDA classifies this vaccine in "Pregnancy category C". There is no safety data on the adjuvanted version of the vaccine. The aim of this prospective cohort study is therefore to evaluate the possible teratogenic effects of the new H1N1 vaccine, both for the non-adjuvanted and the adjuvanted versions of the vaccine.

Organizational Data

- DRKS-ID: **DRKS00000318**
- Date of Registration in DRKS: **2010/03/12**
-

DRKS-ID: **DRKS00000318**
Date of Registration in DRKS: **2010/03/12**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **322/09 , Ethikkommission des Fachbereichs Humanmedizin der Johann-Wolfgang-Goethe-Universität Frankfurt am Main**

Secondary IDs

Health condition or Problem studied

- Free text: **new influenza A(H1N1), spontaneous abortion, preeclampsia, preterm birth, intrauterine growth restriction, congenital disorders**

Interventions/Observational Groups

- Arm 1: **Pregnant woman vaccinated with the new A(H1N1) influenza vaccine during or just before pregnancy**
- Arm 2: **Control: Pregnant women without vaccination or other suspicious medication during pregnancy**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **No treatment**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Possible adverse effects on pregnancy and possible teratogenic effects of the new H1N1 vaccine evaluated in terms of the rate of spontaneous abortion, preeclampsia, preterm birth, intrauterine growth restriction, congenital disorders.

Secondary Outcome

Influence of the time of vaccination on the primary outcome

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/10/01**
- Target Sample Size: **10000**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **14 Years**
- Maximum Age: **50 Years**

Additional Inclusion Criteria

1. Live in Germany
2. Vaccinated with new H1N1 vaccine during pregnancy or just before

Exclusion criteria

Other suspicious drugs during pregnancy or just before

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Bundesministerium für Gesundheit

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Bundesministerium für Gesundheit
Friedrichstraße 108
10117 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2010/03/31**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*