Pregnancy outcome in pregnancies complicated by upper respiratory infections

Published: 23-11-2009
Last updated: 04-05-2024

The aim of the research is to gain more knowledge on the influence upper respiratory infections on the course of pregnancies.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON34899

Source
ToetsingOnline

Brief title
Pregnancy and upper respiratory infections

Condition

- Viral infectious disorders

Synonym
common cold, flu, upper respiratory infections

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Pregnancy, respiratory infection

Outcome measures

Primary outcome

Pregnancy outcome (duration of pregnancy, birth weight, Apgar score, pH / base excess of umbilical cord blood, admission of neonate to neonatal ward)

Secondary outcome

Correlation between maternal and fetal antibodies against viruses causing upper respiratory tract infections.

Study description

Background summary

Last flu season has shown that pregnant women are at increased risk of (complications of) influenza infection. However nearly nothing is known about other upper respiratory infections during pregnancy, neither whether pregnant women are more or less at risk of acquiring them nor if they are at increased risk of complications. Therefor it is usefull to research this so in the future pregnant women can be informed and / or treated.

Study objective

The aim of the research is to gain more knowledge on the influence upper respiratory infections on the course of pregnancies.

Study design

This is a prospective observational cohort study. Pregnancy outcome of women with and without new influenza A H1N1 infection will be compared.

Study burden and risks

The risks and burden associated with participation are nil. The amount of blood sampled is limited. Blood samples are normally taken at times women indergo

venipunture anyway (with exception of those who deliver very fast).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Pregnant women, adults, able to sign informed consent

Exclusion criteria

Incapacitated subjects, women referred during labour

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2009
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO Date:	23-11-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-12-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-07-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30382.041.09