Determinants of Obstetric Outcome: a longitudinal study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON30236

Source
ToetsingOnline

Brief title
DOO

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
complications of pregnancy, pregnancy problems

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Friesland (Leeuwarden)
Source(s) of monetary or material Support: Ministerie van OC&W,GGZ Friesland;uit eigen middelen

Intervention

Keyword: personality, pregnancy complications, risk factors, social factors

Outcome measures

Primary outcome

The primary endpoint is obstetric outcome in terms of complications. Main

predictors of pregnancy outcome that will be investigated are neuroticism,

social and somatic risk factors and mental disease (anxiety and depression).

Secondary outcome

Secundary endpoint is the severity of complications.

Study description

Background summary

About 20% of pregnancies is complicated by some form of maternal or fetal morbidity. Evidence is mounting that besides somatic risk factors, psychological and social factors are involved in the etiology of pregnancy complications. However, the mechanisms that explain how these factors may lead to pregnancy complications have not been identified yet. A better understanding of these mechanisms may contribute to improvement of prevention protocols.

Study objective

Aim of this study is to identify how pregnancy complications can be predicted from the interplay between psychological, social and somatic risk factors. We hypothesize that the personality trait neuroticism predisposes to complications of pregnancy and that this relationship is mediated by social risk factors, somatic disease and mental illness.

Study design

A longitudinal observational design is applied.

Study burden and risks

At 10-14 weeks* gestation, participants complete a series of questionnaires, that target personality, social factors, anxiety, and depression (time investment: 1 hour). At 20, 24, 28, 32, and 36 weeks* gestation anxiety and depressive symptoms are re-assessed (15 minutes), at 32 and 36 weeks in combination with social factors (30 minutes). Questionnaires are sent to the home address of participants and can be returned by mail. To establish the presence of an anxiety and/or depressive disorder a diagnostic interview will be conducted in women with symptom levels above pre-defined cut-off scores (interview by phone, 15 minutes). All assessments are non-invasive and bear no risk with respect to the course or outcome of pregnancy.

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

- Age over 17 years.
- Sufficient control of the Dutch language.
- Singleton pregnancy.
- Gestational age < 98 days.

Exclusion criteria

- Present somatic or mental disease necessitating hospital admission.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	18-12-2006
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL14862.099.06