# 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**

#### **Public**

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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