Multidisciplinary step in the prediction and primary prevention of preterm birth

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

Summary

ID

NL-OMON41673

Source
ToetsingOnline

Brief title
Prevention of Preterm Labour in Low Risk Women (PROPELLOR)

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Lifestyle issues

Synonym
premature labour, preterm birth

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW;projectnummer 209020002

Intervention

Keyword: Premature birth, Prevention and control, Prognosis, Risk Factors

Outcome measures

Primary outcome

Primary outcome is spontaneous preterm delivery before 37 weeks (expected incidence is approximately 5%)

Secondary outcome

Secondary outcome measures are:

- preterm delivery before 28, 32 and 34 weeks

- the number of women that present for signs and symptoms of preterm birth

- referral to secondary/tertiary care for threatened preterm birth

- administration of corticosteroids and tocolysis

- maternal admission days for preterm labour and costs

- time to delivery

- maternal morbidity

- perinatal mortality

- perinatal morbidity (respiratory distress syndrome (RDS), broncho pulmonal dysplasia (BPD), intraventricular haemorrhage (IVH) grade 3 or worse, necrotizing enterocolitis (NEC) stage 2B or higher, periventricular leucomalacia (PVL), rethinopathy of prematurity (ROP), and culture proven sepsis)

- days of admission in neonatal intensive care unit

- financial costs

- long term neonatal outcome (developmentscores)

Study description

Background summary

Preterm birth is the most important cause of neonatal mortality in the Netherlands. In the region around the AMC, we already study, in a multidisciplinary setting, preterm birth in studies and evaluate treatments for threathening preterm labour.
In this study, risk factors for preterm birth will be studied in nulliparous women at present considered to have low risk pregnancies. These risk factors will be linked to the occurence of preterm birth as well as subsequent neonatal outcome. The project is unique in the sense that it integrates factors in the field of public health, factors on labour and physical activity, clinical factors and the subsequent course of pregnancy.
The data will be used to develop and validate a prediction model for preterm birth. This model can be used for the design of intervention studies. This project facilitates a next multidisciplinary step in the prediction and primary prevention of preterm birth.

Study objective

The aim of this study is to study risk factors (in the field of public health and occupation as well as medical technical factors) to enable early detection of pregnant women at increased risk and to integrate these risk factors in a risk prognostic model to enable the identification of pregnant women at increased risk for preterm birth. The data will be collected in an unselected population and their offspring, both short term and long term.
This will then result in answering the following questions:
1. What is the risk of spontaneous preterm birth in the regions Noord-Holland, Flevoland, Gooi- en Vechtstreek en Kennemerland in terms of
- spontaneous preterm birth before 37 weeks?
- spontaneous preterm birth before 34 weeks?
- spontaneous preterm birth before 32 weeks?
2. What is the neonatal mortality and morbidity due to spontaneous preterm birth?
3. Which risk factors contribute to spontaneous preterm birth?
- socioeconomic factors
- ethnic factors
- regional factors
- occupational health, labour and physical activity
- nutrition
- medical history

- biomarkers, including serum samples, bacteriuria and cervical length
4. How do these risk factors interact? Can differences in biomarkers be explained by ethnic, socioeconomic, regional, occupational health and other factors?

Study design

Observational cohort study in the catchment area of the Regional Perinatal Network Northwest Netherlands (Netwerk Geboortezorg Noordwest Nederland).

Study burden and risks

This study is an observational study, so no interventions will take place. Two extra serum samples will be taken, a vaginal and rectal swab will be collected and an extra transvaginal ultrasound measure will be performed. The performed tests are widely used in common obstetrical care, so the extra burden and risks for the women remain very low. Also women will be asked to complete a web-based questionnaires, one in each trimester. In the first trimester filling in takes 30 minutes, the next questionnaires take 10 minutes.

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

Nulliparous women
First visit in midwifery practice before a gestational age of 24 weeks
Low risk pregnancy
Maternal age > 18 years

Exclusion criteria

Multiparous women
First visit in midwifery practice and hospital beyond a gestational age of 24 weeks
High risk pregnancy (indication for referral to 2nd or 3rd line)
Multiple pregnancy
Maternal age < 18 years

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2014
Enrollment:	4000
Type:	Actual

Ethics review

Approved WMO Date:	30-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL43414.018.13