The identification of causal factors for premature delivery in placenta and myometrium

Published: 28-09-2010 Last updated: 30-04-2024

To obtain a durable biobank of placenta, placental bed and myometrium, combined with a good clinical database. The tissue will be used to investigate differences in tissue specific expression between woman who have not gone into labour and deliver...

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

Summary

ID

NL-OMON34279

Source ToetsingOnline

Brief title PANDA-postnataal

Condition

• Pregnancy, labour, delivery and postpartum conditions

Synonym premature labour, preterm delivery

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W, subsidie wordt aangevraagd

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Intervention

Keyword: myometrium, placenta, pregnancy, premature labour

Outcome measures

Primary outcome

Knowledge on transcription regulation in placenta and myometrium relevant for

the delivery process. De results will offer the opportunity to develop

prognsotic markers and rational therapy for threatening premature delivery.

Secondary outcome

none

Study description

Background summary

delivery before 37 weeks of gestation is premature and with a prevalence of 9.6% this affects 14.000 newborns in the Netherlands each year. Prematurity is the leading cause of neonatal mortality and morbidiy and strongly associated with poor neurological and motor development during childhood. premature delivery is usually the consequence of premature rupture of membranes or premature labour. The growing fetaus, the placenta and the myometrium all contribute to the initiation of delivery. The molecular process that initiates delivery however, is not known, there are no prognostic markers available> Treatment is usually only able to delay delivery for a short period of time, as the onset of labour probably occurs weeks before actual labour starts. If labour has started this process is already too far advanced to stop. Detailed knowledge on the molecular events in placenta and myometrium that initiate delivery, is essential to develop prognostic tests and rational and effective treatment.

Study objective

To obtain a durable biobank of placenta, placental bed and myometrium, combined with a good clinical database. The tissue will be used to investigate differences in tissue specific expression between woman who have not gone into labour and deliver through primary caesarean section and women who deliver by secondary caesarean section because of inadequate progression of labour.

Study design

This is an observational study. Pregnant women who undergo a caesarean section will be asked to participate. The tissue samples collected will be udes to investigate protein and mRNA expression profiles.

Study burden and risks

A myometrium biopsy is considered a standard procedure with minimal risk. The duration of the procedure will be extented by a few minutes and the biopsy will not contribute to bloodloss.

Contacts

Public Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Amsterdam NL **Scientific** Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

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Inclusion criteria

Pregnant women who deliver by primary or secundary caesarean section.

Exclusion criteria

HIV positive

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):	28-08-2011
Enrollment:	200
Туре:	Actual

Ethics review

Approved WMO Application type: Review commission:

First submission 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 CCMO **ID** NL32485.018.10