Which factors before and during pregnancy can predict the severity of labourpain? A observational prospective cohort study in women and their partners to the pain threshold before and during pregnancy, constitution, inflammatory status and the relationship with and the character of the partner.

Published: 17-11-2008
Last updated: 11-05-2024

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32180

Source
ToetsingOnline

Brief title
Labour pain: is the severity of pain predictable?

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions

Synonym
labour pain

Health condition

zwangerschapswens

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: inflammatory status, labour pain, pain threshold

Outcome measures

Primary outcome

The proposed study will provide data of the pain threshold before and during

pregnancy and the intensity of pain during labour.

Secondary outcome

Secondary parameters are (pro) inflammatory status, constitution of the woman,

her relationship and the character of the partner.

Study description

Background summary

Pain experienced by women during childbirth is the most intense acute pain. During labour 60 - 80% of the women experiences severe to unbearable pain. Some factors have their positive (self-efficacy, pregnancy course) or negative influence (anxiety, stress and low back pain during menstruation) to the pain intensity. Knowledge about other factors before or during pregnancy that can predict the severity of labour pain are hardly available due to the high global use (> 60%) of epidural analgesia during labour. In the Netherlands, the use of

epidural analgesia is relatively low (± 10%). This study can obtained insights about the pain threshold, pro inflammatory status, constitution of the woman, her relationship and the character of her partner and their impact on the intensity of pain during labour.

Study objective

The primary objective is to examine whether the pain threshold during pregnancy is associated with the intensity of the pain and whether there is difference between before and during pregnancy. In addition, we examine associations between (pro) inflammatory status, the constitution of the woman, the relationship with her partner and the character of her partner.

Study design

The proposed study is an observational prospective cohort study.

Study burden and risks

The burden of the participants consists of measuring the pain threshold (2 x half hours) or the venapuntion (2 x 5 min, 30 ml total) during a home visit and filling out the questionnaires (total 2 hours). Also there is a burden to obtain the VAS during labour.
The risk with participation of the study is small and is related to algometry (haematoma or pain on the pressure point), the venapunction (risk of fainting or haematoma) or filling out the questionnaires (stress) during a home visit.

Contacts

Public
Universitair Medisch Centrum Utrecht

Lundlaan 6
3584 EA Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6
3584 EA Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

pregnancy wish or primigravidity
age from 18 years
control of dutch language
informed consent

Exclusion criteria

Women with rheumatic disorders which are connected with pain e.g. rheumatoid arthritis.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	220

Type:	Anticipated

Ethics review

Not approved

Date:	17-11-2008
Application type:	First submission
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	NL23135.041.08