# Vragenlijst onderzoek met betrekking tot opvattingen ten aanzien van de ruggenprik en angst voor de bevalling in een Nederlandse tweedelijns- en eerstelijns populatie en vergelijking met een Belgische populatie.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON24466

**Source**
Nationaal Trial Register

**Health condition**

beliefs about epidural analgesia, pain catastrophizing, cultural differences

### Sponsors and support

**Primary sponsor:** Maastricht University Medical Centre
**Source(s) of monetary or material Support:** none

### Intervention

### Outcome measures

**Primary outcome**

The primary outcome of this trial is to observe why women prefer, or not, epidural analgesia and the influence of pain catastrophizing thinking.

### Secondary outcome

Secondary outcomes of this trial are cultural differences and differences between first and secondary line.

## Study description

### Background summary

OBJECTIVE:

Epidural analgesia (EA) is an effective method to reduce labour pain, but is not frequently applied in the Netherlands. In this proposal, we determine the beliefs and characteristics of women about epidural analgesial. Besides we want to gain insight in the influence of pain catastrophizing on the experienced pain and fear for labour.

STUDY DESIGN:

Multicentre prospective trial.

STUDY POPULATION:

Term nulliparous and multiparous women with a child in cephalic presentation, and without contraindications for vaginal labour or EA. Patients will be recruited in 3 hospitals in the Netherlands, 2 hospitals in Belgium and 4 midwifery clinics.

INTERVENTIONS:

Women will be asked to fill in 4 questionnaires: A general medical questionnaire, the BEAQ, the PCS and information about epidural analgesia.

OUTCOME MEASURES:

The primary outcome of this trial is to observe why women prefer, or not, epidural analgesia and the influence of pain catastrophizing thinking. Secondary outcomes of this trial are cultural differences and differences between first and secondary line.

SAMPLE SIZE CALCULATION AND DATA ANALYSIS:

The expectation is that fear of childbirth and additional pain are important reasons for choosing analgesia, or at least influence the choice. An expected reason for not choosing analgesia is that it could be detrimental for the (unborn) child.

It is also expected that there will be a difference between the Dutch and Belgian population, because the Netherlands acts conservative and childbirth pain as normal as possible (it belongs') is experienced.

**Study objective**

The expectation is that fear of childbirth and additional pain are important reasons for choosing analgesia, or at least influence the choice. An expected reason for not choosing analgesia is that it could be detrimental for the (unborn) child.

It is also expected that there will be a difference between the Dutch and Belgian population, because in the Netherlands a conservative approach of labor pain is more common. Besides, we expect a difference between the Dutch first line (independant midwife clinics) and Dutch second line (hospital population).

**Study design**

1. Okt-dec 2010: Inclusion;

2. Dec 2010-march 2011: Data-analysis and rapportage.

**Intervention**

Each women with a gestational age of 36-42 weeks is asked to participate. After informed consent is achieved, the woman fill in 4 questionnaires:

1. General medical questionnaire;

2. BEAQ: Beliefs about epidural analgesia questionnaire;

3. PCS: Pain catastrophizing scale;

4. Information about the epidural analgesia questionnaire.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Patients in order to be eligible for the trial, women have to:

1. Be 18 years or older;

2. Bear a singleton child in cephalic presentation;

3. Be under supervision (second line) for their pregnancy in one of the participating centres (Orbis Medisch Centrum Sittard, VieCuri Venlo, Catharina Ziekenhuis Eindhoven, UZ Leuven en ZOL Genk) or by midwifes in participating centres;

4. Have no contraindications for vaginal labour;

5. Gestational age 36-42 weeks.

## Exclusion criteria

Patient in order not to be eligible for the trial, women have to:

1. Be younger than 18 years;

2. Bear twin pregnancy;

3. Have contraindications for vaginal labour;

4. Gestational age less than 36 weeks.

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 25-10-2010 |
| Enrollment: | 600 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 29-10-2010 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL2464 |
| NTR-old | NTR2580 |
| Other | MEC number Atrium Medical Centre Parkstad : 08-T-26 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A