

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	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 analgesia. 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 (independent 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 midwives 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