The randomised epidural analgesia in term delivering women trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26645

Source
NTR

Brief title
TREAT-study

Health condition

epidurale analgesie bij zwangeren. chronische pijn.
epidural analgesia in delivering women. Chronic pain.

Sponsors and support

Primary sponsor: maastricht medical center
department of obstetrics and anesthesiology
Source(s) of monetary or material Support: no funding

Intervention

Outcome measures

Primary outcome

The number of instrumental vaginal deliveries.

Secondary outcome

1. Maternal pain reduction during delivery, as measured on a VAS;

2. The use of oxytocin;

3. The number of caesarean sections;

4. The duration of the second stage of labour;

5. Maternal hypotension, motor block, urine retention, fever;

6. Antibiotics used;

7. Anaesthetics used;

8. Neonatal condition (including Apgar scores and umbilical blood gasses);

9. Maternal experience;

10. Quality of life;

11. Chronic pain after 6 months.

Study description

Background summary

Objective:

Epidural analgesia (EA) is an effective method to reduce labour pain. In this proposal, we determine the beliefs and characteristics of women about epidural analgesia and we asses the impact of a proactive policy of offering EA at the start of labour as compared to a restrictive policy on maternal pain reduction, obstetrical complications, neonatal outcomes and maternal experience of the delivery. Besides we want to gain insight in the influence of pain catastrophizing on the experienced pain and fear for labour. Also we want to investigate if chronic pain after labor and delivery is a problem.

Study design:

Bicentre randomised open label trial. It concerns a pilot study.

Study population:

Term nulliparous and multiparous women with a child in cephalic presentation, and without contraindications for vaginal labour or EA.

Interventions:

Women will be allocated to the EA group or the non-EA group. In the EA group, women are given an EA as soon as they are in labour. In the non-EA (restrictive) group, women receive pain relief only on their explicit request.

Outcome measures:

The primary outcome is the number of vaccuumextractions. Secondary outcomes are the use of oxytocin,maternal pain during labour, the number of instrumental vaginal deliveries, the number of caesarean sections, the duration of the second stage of labour, maternal hypotension, motor block, urine retention, fever, obstetric complications, antibiotics and anaesthetics used, neonatal condition, maternal experience of the delivery and quality of life.

Study objective

The objective of the study is to assess the impact of a proactive policy of offering EA at the start of labour before maternal request in women with a child in occiput presentation allowed to try a vaginal delivery, on maternal pain reduction, obstetrical complications, neonatal outcomes, and maternal experience of the delivery. Furthermore, we want to gain insight on the basis of which characteristics (attributes) women in labour chose for (prefer) epidural analgesia.

Our hypotheses is that the number of instrumental deliveries in both groups is the same (non inferiority trial) (primary outcome).

Study design

1. Baseline at 36 weeks of gestation;

2. During labor;

3. 8 hours, 6 weeks and 6 months after delivery.

Intervention

Women will be allocated at random into two different groups:

1. EA group: These women are given an EA as soon as possible as they are in labour, judged by the attending gynaecologist and based on an effaced cervix with at least 2 cm dilation at vaginal examination;

2. Non-EA (restrictive) group: These women receive pain relief only on their explicit request. According to local preferences, several methods of pain relief are allowed, including EA in case other methods have failed.

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Eligibility criteria

Inclusion criteria

1. Women older than 18 years;

2. Singleton child in cephalic position;

3. Second line supervision for pregnancy in Heerlen or Maastricht;

4. No contraindications for vaginal delivery;

5. No contraindications for epidural analgesia.

Exclusion criteria

1. Women younger than 18 years;

2. Bear twin pregnancy;

3. Contraindications for vaginal delivery;

4. Contraindications for epidural analgesia;

5. Referral by midwife during labour.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	488
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-01-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32404
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2596
NTR-old	NTR2724
CCMO	NL22276.096.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32404

Study results

Summary results
Prevalence and predictors of chronic pain after labor and delivery, Johanna M.F.W. Vermelis, Martine M.L.H. Wassen, Audrey A.A. Fiddelers, Jan G. Nijhuis and Marco A.E. Marcus
Current Opinion in Anaesthesiology 2010, 23:295–299.