Comparing patient satisfaction and costs between epidural and remifentanil during labour in low risk pregnant women.
Vergelijking van tevredenheid en kosten tussen epidurale anesthesie met remifentanil bij laag risico zwangeren.

No registrations found.

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

Summary

ID

NL-OMON20738

Source
NTR

Brief title
Ravel 2 study/Ravel eerste lijn studie

Health condition

This study will assess in women with a request for pain relief during labor the costeffectiveness
of RPCA as first choice treatment compared to EA.
Epidurale anesthesie meest effectieve vorm van pijnbestrijding. Echter de tevredenheid van de patient tav epidurale anesthesie vergeleken met remifentanil, in dit geval laag risico zwangere, is niet bekend.

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: Verloskundig Consortium

Intervention

Outcome measures

Primary outcome

Costeffectiveness of RPCA as first choice treatment compared to EA in low risk pregnant women.

Secondary outcome

1. Pain appreciation;

2. Patient satisfaction;

3. Pain scores;

4. Maternal and neonatal side effects.

Study description

Background summary

In addition to Ravel (1) study, the Ravel 2 study started. To compare the differences in respect of paincontrol and costs, between the low risk pregnant women and women with a medical indication for pregnancy/delivery.

Study objective

We hypothesize that RPCA is as effective in reducing pain relief scores as EA, with lower costs and easier achievement of 24 hours availability of pain relief for low risk women in labor.

Study design

The endpoint: Costs of both interventions, remifentanil PCA and epidural analgesia for pain relief during labor.

Timepoint: Starting at the onset of labor and ending ten days after delivery.

The secondary endpoints: Maternal parameters:

1. Pain scores (timepoint: end of delivery);

2. Pain appreciation scores (timepoint 6 weeks after delivery);

3. Side effects (timepoint: end of delivery).

Endpoint neonatal outcome (timepoint discharge home).

Intervention

Epidural anesthesia versus remifentanil.

First line pregnant women will be included. They will know which form of treatment they will get once they request pain control. If they don't use pain control they will be part of the control group. During delivery pain- and satisfactionscores will be taken every hour. 2 hours postpartum another satisfactionscore will be taken regarding experienced pain.

Before randomisation and 6 weeks postpartum 2 questionnaires will be taken (Wijma $ HADS). Also, 10 days postpartum, a questionnaire will inventory the costs.

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Eligibility criteria

Inclusion criteria

1. Age >18 years;

2. ASA physical status I or II;

3. Low risk pregnant women.

Exclusion criteria

1. Drug allergy: History of hypersensitivity to opioid or local anesthetic;

2. Substances;

3. Labor before 32 weeks or after 42 weeks of gestation;

4. Initial maternal SpO2 of less than 95%;

5. Initial maternal temperature of 38C or higher;

6. Prior administration of regional of opioid analgesia (during this delivery).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-10-2012
Enrollment:	408

Type:	Anticipated

Ethics review

Positive opinion

Date:	05-11-2012
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	NL3532
NTR-old	NTR3687
Other	METC LUMC : P10.240
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A