Is remifentanil patient controlled analgesia 20 micrograms a sufficient dose for pain relief during labour? A prospective study.

No registrations found.

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

Summary

ID

NL-OMON23915

Source
NTR

Brief title
TBA

Health condition

None

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The percentage of women receiving remifentanil PCA 20 micrograms without a dose increase

during delivery.

Secondary outcome

- Maternal measurements and side effects: visual analogue scale (VAS) pain score, saturation and respiratory rate.
- Neonatal measurements and side effects: Apgar score, umbilical cord blood gas and necessity for the involvement of pediatrician directly postpartum due to sedation-related causes.
- Patient experience with remifentanil postpartum.

Study description

Background summary

Since 2005 remifentanil has been used as an analgesic in the obstetric world. Remifentanil is an opioid analgesic, which is attractive for use based on its pharmacodynamics and -kinetics. The 'Standard Operating Procedure (SOP) Remifentanil' frames the minimum care required for the use of remifentanil in Dutch clinics. The SOP describes three bolus doses, but does not provide adequate justification for the starting dose of 30 micrograms. There may be a patient population that experiences adequate pain relief with remifentanil bolus 20 micrograms, the lowest dose within the range of the SOP. The potential benefit of this is a lower incidence of side effects.

Objective: To investigate whether remifentanil PCA 20 micrograms, with a lock-out time of 3 minutes, is an effective dose for pain relief during labour.
Question: Is (and for whom) remifentanil PCA 20 micrograms a sufficient dose for pain reduction during labour?
Design: Prospective non-experimental study.
Research group: Childbearing women who use remifentanil as an analgesia for pain relief between 8 April 2019 and 31 December 2019 in the Ikazia hospital (Rotterdam, Netherlands).
Primary outcome measure: The percentage of women who receive remifentanil PCA 20 micrograms without a dose increase during delivery.
Secondary outcome measures: Maternal and neonatal side effects and patient experience with remifentanil postpartum.
Data analysis: Using IBM SPSS Statistics 25.

Study objective

Remifentanil PCA 20 micrograms is an effective dose for pain relief in labour.

Study design

- VAS (0-10): before start remifentanil, after 30min, 60min and then every hour.

- Satisfaction with pain relief (0-10): after 30 min, 60 min and then every hour.
- Saturation: before start remifentanil, in the first hour every 10 minutes and then every 30 minutes.
- Respiratory rate: before start remifentanil, in the first hour every 10 minutes and then every 30 minutes.
- Apgar: at 1, 5 and 10 minutes directly postpartum.
- Umbilical cord blood gas: directly postpartum.
- Patient experience: short survey (4 questions) 4 hours postpartum.

Intervention

When there is a pain relief request during labour and the woman choose for remifentanil: Remifentanil PCA starting at 20 micrograms IV with a lock-out time of 3 minutes. When this is insufficient the dose can be increased up to 30 micrograms or 40 micrograms, also with a lock-out time of 3 minutes.

The need for additional pain relief, by increasing remifentanil dose or switching to epidural analgesia, is determined in two ways:
- After starting remifentanil the woman is asked if she experiences sufficient pain relief at 30 minutes, 60 minutes and then every hour.
- The woman is counseled that she may ask for more pain relief at any time if she experiences insufficient pain relief (pain breakthrough).

Contacts

Public
Ikazia ziekenhuis
Britt Boender

010-2902308
Scientific
Ikazia ziekenhuis
Britt Boender

010-2902308

Eligibility criteria

Inclusion criteria

- Women in active phase of labour (4cm dilatation or more, 3 contracties per 10 minutes or

more)
- American Society of Anesthesiologists (ASA) classification I or II
- Singleton term pregnancy, cephalic presentation

Exclusion criteria

- Hypersensitivity to opioids
- Women with opioid abuse or addiction
- Use of opiates within 4 hours for the administration of remifentanil
- Women who had epidural analgesia during this labour
- Inability to provide informed consent
- Simultaneous use of magnesium sulfate
- Morbide obesitas (BMI >40)
- Abnormal CTG for starting remifentanil, assessment according to the Fédération Internationale de Gynécologie et d'Obstétrique (FIGO) classification.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-04-2019
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	09-04-2019
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	NL7652
Other	Ikazia : IZ/651/SW1912

Study results