Epidural analgesia versus Remifentanil PCA during labour

Published: 15-10-2007
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To compare Remifentanil PCA with epidural anesthesia among healthy nulligravidia during labor.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON31070

Source
ToetsingOnline

Brief title
OER-study

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
labor pain control, pain during birth

Research involving
Human

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Epidural, Labor, Pain, Remifentanil

Outcome measures

Primary outcome

Patients' satisfaction

Secondary outcome

Outcome of the infant, APGAR.

Vacuum or forceps deliveries

Study description

Background summary

In the Netherlands analgesia during labor consists of Pethidin im or epidural analgesia. Both methods have their side effects. Pethidin has a half life of 3-4 hours and can be quite sedative and can cause impaired thinking with hallucinations. Especially the respiratoiry depression may be a threat to the infant. With the introduction of the Remifentanil PCA on our OBGY ward we, as in the current literature, experience less opiod side effects as seen with Pethidin. Remifentanil has a half life of only a few minutes. Therefore, we hypothise that remifentanil is an attractive replacer of Pethidin, and in addition, a competitive treatment of epidural analgesia. Introducing epidural analgesia on the ward often causes a delay since an anesthesiologist is required. Moreover, patients are restricted to bed, somethimes describe the feeling of not being part of the labor process and increased risk for vacuum or forceps delivery and unexplained fever.

Study objective

To compare Remifentanil PCA with epidural anesthesia among healthy nulligravidia during labor.

Study design

Two groups of healthy nulligravida, the study group with Remifentanil PCA, and the control group with epidural anesthesia are compared.

Intervention

The study group receives a Remifantanil PCA, which will be connected to the IV

line. The control group receives a standard epidural procedure for catheter placement.

Study burden and risks

Both methods of analgesia are applied methods of analgesia during labor. There are no expected increased risks associated.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

nulligravida
without serious systemic disease

in partu, less than 6cm dilatation
healthy
in labour

Exclusion criteria

American Society of Anesthesiologists (ASA) >2
(pre)eclampsia
HELLP syndrome
serious diabetic gravidarum
infection
placenta praevia
psychiatric disorder

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2008
Enrollment:	246
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ultiva

Generic name:	remifentanil
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-10-2007
Application type:	First submission
Review commission:	METC Vrije Universiteit Medisch Centrum (Amsterdam)
Approved WMO Date:	06-02-2008
Application type:	First submission
Review commission:	METC Vrije Universiteit Medisch Centrum (Amsterdam)
Approved WMO Date:	16-09-2010
Application type:	Amendment
Review commission:	METC Vrije Universiteit Medisch Centrum (Amsterdam)

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
EudraCT	EUCTR2007-005424-33-NL
CCMO	NL17308.029.07
Other	volgt