Patient controlled analgesia i.v. with morphine versus continuous epidural analgesia with bupivacaïne and sufentanil as pain relief after caesarean section.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Postpartum and puerperal disorders
Study type	Interventional

Summary

ID

NL-OMON44865

Source
ToetsingOnline

Brief title
GAstudy

Condition

- Postpartum and puerperal disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
pain relief after caesarean section

Research involving
Human

Sponsors and support

Primary sponsor: Kennemer Gasthuis
Source(s) of monetary or material Support: geen

Intervention

Keyword: caesarean section, epidural, pain relief, PCA

Outcome measures

Primary outcome

Mobilization, how many hours after cesarean section does the patient stand

beside the bed?

VAS pain score post partum.

Secondary outcome

Time between caesarean section and stop PCA or CEA in hours.

Time between caesarean section and discharge in hours.

Use of oral pain relief.

Side effects: nausea and vomitting, sedation score, pruritis.

Study description

Background summary

The last decennia the number of caesarean sections has risen considerably.
In the Eighties around 10% of the deliveries ended in a caesarean section.
Nowadays an averge of 15-20% caesarean sections is the norm. In Holland we have a rapid turnover, as women with a normal uncomplicated vaginal delivery are discharged within hours after child birth. After a caesarean section women are allowed to stay 72 hours in the hospital
Good pain relief is important after a caesarean section to give the mother a chance to bond with her child. By being able to mobilize, she can take care of her baby herself. By achieving an early discharge, she can go home and take over control completely. She will also have a home help the first week. Good painrelief also shouldn*t make mothers sleepy or drowsy, so they could miss

valuable first impressions. Last but not least the hospital would benifit from an earlier discharge, because of the high turnover in the labour wards. In the Netherlands having 180.000 deliveries per annum, it would with the current section rate cocern 36.000 post natal cares.
Discharge shouldn*t be hindered by controlable factors as pain.

Study objective

We would like to research wether there is a difference in time of mobilization between women getting iv PCA with Morphine (PCA)as opposed to women getting continuous epidural analgesia (CEA)with bupivacaine and sufentanil.
We expect that the PCA will be as effective as CEA, but that women will mobilize earlier and therefor be able to look after their child sooner. We will perform the research within our own hospital.

Study design

The proposed study is a randomized study on location with control group. The Kennemer Gasthuis has a minimum of 1500 high risk deliveries per annum. The caesarean section percentage is around 20 %. The amount of elective caesarean sections was 173 in 2012.
The research population will be asked to participate in the research at 34 weeks pregnancy at theclinic.
Group A will get PCA iv with morphine 2mg/ml, bolus 2 mg, lock out period 5 minutes, maximum 30 mg in 4 hours. Group B will get continuous epidural analgesia (CEA) with bupivacaine 0,125% (50 ml) combined with sufentanil 50 micrograms= 1 ml, infusion rate 4-10 ml/hr., starting with 6 ml/hr or higher.

Intervention

Group A will get iv PCA with morphine 2mg/ml, bolus 2 mg, lock out period 5 minutes, with a maximum of 30 mg in 4 hours.
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Study burden and risks

Minimal, restricted to only a few questions at randomisation and during admission in hospital.
Both methods of pain relief are standard for post-operative pain relief in our hospital and in the Netherlands.

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

ASA1 and ASA2 pregnant women scheduled for primary caesarean section

Exclusion criteria

no informed consent
pre-eclampsia
coagulation disorders
ASA 3 and more
allergy for morphine, sufentanil or bupivacaine
local infection on the site of injection of the epidural.
increased intracranial pressure.

uncorrected hypovolemia.
relative contra-indications for epidural such as:
neurological disorders like multiple sclerosis,
malformation of the back,
history of back operations,
systemic infections.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2015
Enrollment:	70
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Morphine
Generic name:	Morphine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	08-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2013-00-5168-2-NL
CCMO	NL45365.094.13

Study results