ISRCTN12122492 https://doi.org/10.1186/ISRCTN12122492

Obstetric analgesia: a comparison of patient controlled pethidine, remifentanil and fentanyl in labour

Submission date	Recruitment status	[ ] Prospectively registered
14/02/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/02/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/11/2008	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M R Douma

Contact details
Bronovo Hospital
Department of Obstetrics and Gynaecology
Bronovolaan 5
The Hague
Netherlands
2597 AX
+31 (0)61 427 6591
maritdouma@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR543

Study information

Scientific Title

Acronym
Baringspijn

Study objectives
The hypothesis of this study is that the new opioid remifentanil will provide less side-effects and better pain relief during labour, than the conventional opioids fentanyl and pethidine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Double-blind randomised active controlled parallel group clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Labour pain

Interventions
The following drugs are used in a patient controlled method:
1. Remifentanil - 40 µg for 2 minutes, total dosage: 1200 µg/h
2. Pethidine - loading dose of 50 mg, then 5 mg for 10 minutes, total dosage: 200 mg
3. Fentanyl - loading dose of 50 µg, then 20 µg for 5 minutes, total dosage: 240 µg/h

Medication will be started in active labour and will be continued until complete dilation of the cervix is achieved. Baseline non-invasive measurements will be made, including maternal blood pressure, heart rate, respiratory rate and pulse oximetry. Measurements will be recorded every 30 minutes. Also, an observer sedation score will be recorded every 30 minutes.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pethidine, remifentanil, fentanyl

Primary outcome measure
1. Quality of pain relief determined by Visual Analogue Scale, patient controlled analgesia (PCA) demands/rewards and the number of patients crossing over to epidural analgesia. Pain scores will be assessed every hour.
2. Patient satisfaction, assessed every hour
3. Foetal outcome as determined by Apgar, NACS and requirement for naloxone, taken after delivery
4. Presence of opioid substances in umbilical and maternal blood samples, taken after delivery

Secondary outcome measures
No secondary outcome measures

Overall study start date
10/08/2005

Completion date
01/09/2006

Eligibility

Key inclusion criteria
1. Aged at least 18 years old
2. Between 37 and 42 weeks of gestation
3. American Society of Anaesthesiologists (ASA) physical status I or II

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria

1. ASA physical status greater than or equal to III
2. Obesity (body mass index [BMI] equal or more than 40 kg/m^2)
3. Substance abuse history
4. High risk patients: including pre-eclampsia (diastolic pressure equal or more than 100, proteinuria), hepatic insufficiency or renal failure, severe asthma, poorly controlled diabetes mellitus
5. Premature labour
6. Drug allergy; history of hypersensitivity to opioid substances

Date of first enrolment
10/08/2005

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Bronovo Hospital
The Hague
Netherlands
2597 AX

Sponsor information

Organisation
Bronovo Hospital (The Netherlands)

Sponsor details
Department of Obstetrics and Gynaecology
Bronovolaan 5
The Hague
Netherlands
2597 AX

Sponsor type
Hospital/treatment centre

Website
http://www.bronovo.nl/Bronovo/en-GB/bronovo/

ROR

https://ror.org/03r781319

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bronovo Hospital (The Netherlands) - research funds

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration