# A comparison of pethidine/meperidine intramusculary and remifentanil patient-controlled analgesia during labor in Westfriesgasthuis

Published: 05-10-2007
Last updated: 08-05-2024

The following hypotheses will be tested:Hypothese a: Remifentanil PCA gives a better labour satisfaction than pethidine/meperidine i.m.Hypothese b: Remifentanil PCA gives a better pain-relief during labour, than pethidine/meperidine intramuscularly....

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Pregnancy, labour, delivery and postpartum conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON30677

**Source**
ToetsingOnline

**Brief title**
PCA remifentanil during labor

### Condition

- Pregnancy, labour, delivery and postpartum conditions

**Synonym**
contraction-pain, pain during labour

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Westfries Gasthuis

**Source(s) of monetary or material Support:** Westfries Gasthuis

## Intervention

**Keyword:** labour, patient-controlled analgesia, pethidine/meperidine, Remifentanil

## Outcome measures

### Primary outcome

Patient satisfaction

### Secondary outcome

Safety for mother and child including: maternal saturation, respiratory rate

and bloodpressure, neonatal Apgar scores and saturation.

Painrelief, measured by maternal VAS-scores.

# Study description

### Background summary

Good pain relief during labour is important. Current methods are meperidine/pethidine intramuscularly or epidural analgesia. To overcome the side effects of both methods, new ways of peripartum painrelief are sought. The short-acting opiod remifentanil i.v. seems a good alternative.

### Study objective

The following hypotheses will be tested:

Hypothese a: Remifentanil PCA gives a better labour satisfaction than pethidine/meperidine i.m.

Hypothese b: Remifentanil PCA gives a better pain-relief during labour, than pethidine/meperidine intramuscularly.

Hypothese c: Remifentanil PCA has less disadvantages for the newborn than pethidine/meperidine i.m.

Hypothese d: Remifentanil PCA has as much disadvantages for the parturient as

pethidine/meperidine i.m.

### Study design

a prospective randomised study

### Intervention

Group A: painrelief with Remifentanil i.v. using PCA
Group B: painrelief with Pethidine i.m. (= standard treatment)

### Study burden and risks

Possible side effects of Remifentanil are reduced ventilatory rate or apnea with or without reduced oxygen saturation. The elimination half time of Remifentanil is short. Normal breathing is expected to return within 5 to 10 minutes from the last infusion. An algorithm was made for how to act in case of desaturation. Midwifes were trained to use the algorithm.

## Contacts

**Public**
Westfries Gasthuis

Maelsonstraat 3,
1624 NP Hoorn
Nederland
**Scientific**
Westfries Gasthuis

Maelsonstraat 3,
1624 NP Hoorn
Nederland

## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Pregnant and ASA1, women in labor in Westfries gasthuis, planned vaginal delivery, informed consent parturient, a term pregnancy (37+0 till 42+0 weeks), unborn lies in head-down-position, the unborn has no congenital abnormalities

## Exclusion criteria

Pregnant woman requesting epidural analgesia or undergoing epidural analgesia, pregnancy is not a term (<37+0 or >42+0 weeks), kwown allergie for remifentanil, paturient who feels she does not have right amount of time to consider enrolling in this study, other fetal positions than head down, fetal congenital abnormalities

# 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: | Recruitment stopped |
| Start date (anticipated): | 12-11-2007 |
| Enrollment: | 274 |

| | |
|---|---|
| Type: | Anticipated |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | meperidine/pethidine |
| Generic name: | meperidine/pethidine |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | ultiva |
| Generic name: | remifentanil |
| Registration: | Yes - NL outside intended use |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 05-10-2007 |
| Application type: | First submission |
| Review commission: | METC Noord-Holland (Alkmaar) |
| Approved WMO Date: | 05-11-2007 |
| Application type: | First submission |
| Review commission: | METC Noord-Holland (Alkmaar) |

## 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 | EUCTR2007-000736-10-NL |
| CCMO | NL16109.094.07 |