The PaPa Trial: Paracetamol as an adjunct to intraPartum Remifentanil/PCA. An RCT of multimodal pain management during labor.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24756

Source
Nationaal Trial Register

Brief title
PaPa Trial

Health condition

Labour pain

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Remifentanil bolus requests and actual administered Remifentanil doses at 30, 60, 90, 120,

150, 180 minutes from zerotime: start of treatment with Remifentanil and either Paracetamol IV or Placebo.

Secondary outcome

Maternal parameters: Need for oxygen administration, frequency of vomiting, time to full dilatation in minutes from start of pain treatment,
Neonatal parameters: Apgar Score≤7 after 5 minutes, Arterial pH level <7.20

Study description

Background summary

SUMMARY: The PaPa Trial: Paracetamol as an adjunct to intrapartum Remifentanil/PCA. An RCT of multimodal pain management during labour.
Rationale: Paracetamol is the primary option for treatment of acute pain. There is little research in obstetrics on the effect of Paracetamol on labour pain. In the Netherlands, the primary choice for treating labour pain is epidural analgesia, followed by Remifentanil/ Patient Controlled Analgesia. The moment Remifentanil was introduced in Dutch obstetrical care, intravenous Paracetamol was not yet available on the Dutch market. Complications with Remifentanil use are rare, but severe: desaturation, hypopnoea and bradycardia. More is known nowadays about multimodal pain management. Paracetamol might reduce opioid use when used as add-on pain medication combined with Remifentanil.
Objective: Primary objective: to research if Paracetamol ensures lower opioid intake when added to Remifentanil as intra-partum pain management.
Secondary objectives: monitoring opioid requests and administered doses of Remifentanil in an intervention (Paracetamol as add-on pain treatment) and control (Placebo combined with Remifentanil) group.
Study design: Single centre double-blind placebo controlled intervention study.
Study population: Healthy women in labour, > 18 years of age.
Intervention: The intervention group receives 1000 mg intravenous Paracetamol (Paracetamol Fresenius Kabi 10 mg/ml, total amount 100 ml) in 15 minutes combined with Patient Controlled Analgesia/ Remifentanil according to protocol. The control group receives a placebo: 100 ml Saline in 15 minutes combined with Patient Controlled Analgesia/ Remifentanil according to protocol.

Main study parameters/endpoints: Remifentanil bolus requests and actual administered Remifentanil doses. Secondary end points: need for oxygen administration, frequency of vomiting, time to full dilatation in minutes from start of pain treatment, Apgar Score.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Counselling for enrolment in the study might be a burden for the labouring woman. However, when need for pain treatment arises, counselling for Epidural Analgesia vs. Remifentanil/ PCA will take place anyhow. Further, the burden is minimal: number of

Remifentanil requests and actual administered doses can be read from the infusion pump. The expectation is that the labouring woman will benefit from opioid reduction, with less desaturation, hypopnoea and bradycardia and therefore less need for administration of oxygen. Also, there is research on possible shorter duration of the dilatation process when Paracetamol is used as intra-partum pain management. Adverse effects of Paracetamol are rare.

Study objective

Adding Paracetamol to treatment with Remifentanil/ Patient Controlled Analgesia for management of labour pain ("multimodal pain management") reduces opioid (Remifentanil) consumption

Study design

30, 60, 90, 120, 150, 180 minutes from zerotime: start of treatment with Remifentanil and either Paracetamol IV or Placebo.

Intervention

Combining 1 gram Paracetamol intravenously with Remifentanil as intrapartum pain management.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following

criteria:
• Pregnant, in labour, >3 centimetres dilatation.
• Pain request during labour, medication of choice: Remifentanil/ PCA.
• Age 18 years and older.
• Able to understand the written and verbal information about the PaPa Trial.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Refusal for participation in the PaPa Trial
• No adequate communication possible (e.g. language barrier)
• Use of other opioids, e.g. Pethidine of epidural analgesia <4 hours prior to start of Remifentanil as pain management.
• Hypersensitivity for Paracetamol.
• Liver- of kidneydiseases
• Alcohol abuse
• Glucose-6-phosphate dehydrogenase
• Use of other medication that contains Paracetamol
• Severe nutritional deficiency

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2020
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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	NL7863
Other	METC Zuidwest Holland : ***

Study results