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

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Primary objective: to research if Paracetamol reduces Remifentanil use when added to Remifentanil/PCA pain management during labour. Patients: Women in labour, using Remifantanil as pain management Intervention: Paracetamol intravenous (1 gram,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON49620

Source
ToetsingOnline

Brief title
The PaPa Trial

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions

Synonym
contractions, Labour pain

Health condition

Pijn/ pijnbehandeling

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Subsidie wetenschapscommissie (WAC) Reinier de Graaf

Intervention

Keyword: Intrapartum, Multimodal, Pain Management, Paracetamol

Outcome measures

Primary outcome

The sample size calculation will be performed on the primary outcome:

administered Remifentanil doses after 60 minutes. Further analysis will be

performed on 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

Paracetamol is the primary option for treatment of acute pain.In the Netherlands, the primary choice for treating labour pain is epidural analgesia, followed by Remifentanil/ Patient Controlled Analgesia. The limited research of the use of Paracetamol for management of labour pain shows that Paracetamol provides similar pain relief, with fewer side effects, compared to Tramadol or

Pethidine.One study shows that Paracetamol as an adjunct to Patient Controlled Epidural Analgesia shows lower opioid consumption compared to Saline as adjunct. Also, duration of labour might be shortened when Paracetamol is used intrapartum.The moment Remifentanil was introduced in the Dutch obstetrical care, intravenous Paracetamol was not yet available on the Dutch market. Complications with use of Remifentanil are rare, but severe: desaturation, hypopnoea and bradycardia. Studies concerning postoperative multimodal pain management show that adding Paracetamol to treatment with opioids reduces opioid use. Paracetamol might reduce Remifentanil use when added to treatment as intrapartum pain management as Patient Controlled Analgesia.

Study objective

Primary objective: to research if Paracetamol reduces Remifentanil use when added to Remifentanil/PCA pain management during labour.

Patients: Women in labour, using Remifantanil as pain management
Intervention: Paracetamol intravenous (1 gram, Paracetamol Fresenius Kabi 10 mg/ml)
Control: Placebo intravenous (100 ml Saline)
Outcome: Remifantanil/PCA requests and administered doses

Study design

Single centre double-blind randomised placebo controlled intervention trial.

Study burden and risks

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.

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

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

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 Acetaminophen/ Paracetamol

Severe nutritional deficiency

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2020
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Perfalgan, Perfusalgan
Generic name:	Paracetamol
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:	06-11-2019

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	07-12-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2019-002825-31-NL
CCMO	NL70766.098.19

Study results

Date completed:	11-12-2020
Actual enrolment:	79

Summary results
Trial is onging in other countries