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

Gepubliceerd: 02-07-2019 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24756

Bron
Nationaal Trial Register

Verkorte titel
PaPa Trial

Aandoening

Labour pain

Ondersteuning

Primaire sponsor: Not applicable
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	11-06-2020
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7863
Ander register	METC Zuidwest Holland : ***

Resultaten