The efficacy of intravenous versus rectal paracetamol: A randomized, prospective, double-blind placebo-controlled study

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1)to compare the analgesic efficacy of intravenous versus rectal paracetamol as assessed by VAS scores, PCA morphine consumption.2)To assess the pharmacokinetic profile of intravenous and rectal paracetamol by intravenous plasma paracetamol and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30232

Source
ToetsingOnline

Brief title
rectal versus intravenous paracetamol

Condition

- Other condition

Synonym
postoperative pain management

Health condition

postoperatieve pijnbestrijding

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: eigen budget

Intervention

Keyword: acetaminophen, intravenous, paracetamol, rectal

Outcome measures

Primary outcome

1)Number of requests of PCA during 24 h.

2)Visual analogue scale (100 mm) for pain.

3)Incidence of nausea/vomting, pruritus, hypotension, resp.depression

(SpO2<95% and ventilatory frequency <10) or sedation (using a 10 point sedation

scale) and Ramsey-score.

4)Overall patient satisfaction with pain treatment (5 point scale)

5)Pharmacokinetic data of paracetamol by intravenous blood samples

6)Intravenous morphine concentration and metabolites by iv samples.

Secondary outcome

none

Study description

Background summary

Paracetamol is the cornerstone in multimodal postoperative analgesia. With the exception of contra-indications such as allergy, paracetamol is the basis of every postoperative analgetic regimen.Paracetamol is administered either as tablets or suppositories. Recently, an intravenous formulation has become available.

Study objective

1)to compare the analgesic efficacy of intravenous versus rectal paracetamol as assessed by VAS scores, PCA morphine consumption.
2)To assess the pharmacokinetic profile of intravenous and rectal paracetamol by intravenous plasma paracetamol and intravenous plasma morphine concentrations.

Study design

A randomized, prospective, double-blind placebo-controlled study.

Intervention

Intravenous, rectal paracetamol or placebo and PCA morphine.

Study burden and risks

During the study period there ten blood samples will be taken.

Contacts

Public
Academisch Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
Nederland
Scientific
Academisch Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

ASA class I-III
Patients undergoing lower abdominal laparotomies under general anesthesia
older tha 18 years
men and women

Exclusion criteria

Patients with a BMI >30.
Participation in a trial on investigational drugs within 3 months prior to the study.
Known hypersentivitity to paracetamol.
Known hypersentivitity to opioids.
Known history of hepatic, renal disease or other disease as judged by the investigators.
Those receiving chronic analgesic therapy.
Inability to perform VAS score.
Pregnancy or lactation.
Alcohol or drug abusus or history of alcohol/drug abusus.
Impaired liver function.
Any other reason which in the opinion of the investigator makes the patient unsuitable for participation in the study.

Study design

Design

Study type:	Interventional
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):	01-11-2007
Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	paracetamol
Generic name:	acetaminophen
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	perfalgan
Generic name:	acetaminophen/paracetamol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	29-05-2007
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2006-004578-29-NL
CCMO	NL14197.058.06