A pharmacokinetic study of intravenous paracetamol in patients after cardiac surgery

Published: 29-05-2006
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The objective of the study is to investigate the plasma concentrations of paracetamol after an iv infusion using a model-derived infusion schedule.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON30132

Source
ToetsingOnline

Brief title
PK of iv paracetamol after cardiac surgery

Condition

- Cardiac therapeutic procedures

Synonym
post-operative pain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: intravenous, Paracetamol, pharmacokinetics

Outcome measures

Primary outcome

Paracetamol concentrations

Secondary outcome

None

Study description

Background summary

Intravenous (iv) paracetamol is increasingly used as an adjunct analgesic to limit the perioperative use of opioids, although the results of studies addressing this issue show ambiguous results. It may well be that insufficient paracetamol concentrations obtained after the standard infusion regimen (1 gram given over 20 min) may be responsible for this. It is generally assumed that effective concentrations are between 10-20 mg/l. In-house TDM data suggest that the paracetamol concentration drops below the presumably effective range after approximately 2 hours. Therefore a study is proposed to prospectively validate the theoretical infusion regimen.

Study objective

The objective of the study is to investigate the plasma concentrations of paracetamol after an iv infusion using a model-derived infusion schedule.

Study design

Open PK study

Intervention

IV paracetamol as continuous IV infusion (routine practice is IV bolus administration)

Study burden and risks

As the only change compared to routine clinical practice is the duration of the infusion of paracetamol and the study requires a total amount of ~65 ml blood to be taken, the burden and the risks associated with participation in this study is considered to be minimal (or even negligible)

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

patients scheduled for elective cardio-surgery
over 18 years of age
able and willing to consent

Exclusion criteria

clinically significant hepatic dysfunction, body weight above 100 kg, known hypersensitivity to paracetamol or pregnancy

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-01-2008
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Perfalgan
Generic name:	paracetamol for iv use
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	29-05-2006
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	EUCTR2006-001290-23-NL
CCMO	NL12397.058.06