

Comparing oral and intravenous paracetamol plasma levels when given as pre-medication for peri-operative analgesia

Submission date 19/06/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/11/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/03/2013	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
06/Q2002/25

Study information

Scientific Title

Acronym

Paracetamol

Study objectives

The hypothesis is that in the peri-operative setting gastric emptying is delayed and that the absorption of oral paracetamol preparation is therefore unreliable. It might be more appropriate to use the intravenous route and if so will become apparent during the study.

The aim of this research study is to compare plasma levels of the intravenous and oral paracetamol preparations when used as pre-emptive analgesia. We wish to establish whether the intravenous preparation, the oral preparation or both achieve therapeutic plasma levels intra-operatively. Use of paracetamol as a pre-emptive analgesia is well established in previous studies, which have shown that pre-emptive analgesia reduces post-operative pain more than when analgesia is used solely post-operatively and others have shown that peri-operative use of paracetamol also reduces opioid use.

Therefore, is intravenous paracetamol more effective than the oral preparation when given as a pre-medication?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Peri-operative analgesia

Interventions

Group A: Intravenous injection equivalent to one gram paracetamol given by the researchers immediately prior to induction of anaesthesia in theatre.

Group B: One gram oral paracetamol prescribed on the ward and given by the nursing staff or researchers one to two hours before induction of anaesthesia.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Paracetamol

Primary outcome(s)

Therapeutic plasma level of paracetamol (when the plasma level is 10 - 20 mg/l [the test will be at 30 minutes post induction of anaesthesia])

Key secondary outcome(s)

Non-therapeutic plasma level of paracetamol

Completion date

01/08/2007

Eligibility**Key inclusion criteria**

1. Assessment of fitness as indicated by the American Society of Anesthesiologists (ASA) grades I and II
2. Age group 16 to 75 years
3. All patients listed for elective surgery by Mr P Robinson on a Thursday for Ear, Nose & Throat surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients refusing to participate in study
2. Patient unable to take an oral preparation
3. Cases shorter than one hour
4. Patients already taking a paracetamol containing drug combination, or have taken in the last 12 hours
5. Patients with a history of paracetamol allergy, hypersensitivity or previous reaction/serious adverse reaction
6. Children under the age of 16
7. Patients unable to understand or give consent to participation in the study; incapable adults, psychiatric/medical disorder able to modify patient compliance
8. Pregnant or breastfeeding
9. History of complete non-responsiveness to acetaminophen
10. Pancreatic disease in the previous 12 months
11. Impaired liver/kidney function
12. Patients that might pose an infection risk to staff due to blood products

Date of first enrolment

01/08/2006

Date of final enrolment

01/08/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Consultant Anaesthetist**

Bristol

United Kingdom

BS10 5NB

Sponsor information

Organisation

North Bristol NHS Trust (UK)

ROR

<https://ror.org/036x6gt55>

Funder(s)

Funder type

Government

Funder Name

North Bristol NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2011		Yes	No