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Does paracetamol given by mouth before wisdom tooth extraction give equal pain relief compared to paracetamol given by intravenous infusion?

Submission date 22/01/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/05/2008	**Overall study status** Completed	
Last Edited 12/12/2012	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RPC179

Study information

Scientific Title
A comparison of pre-medication with oral paracetamol versus intravenous paracetamol given at time of induction for post-operative analgesia following wisdom tooth extraction

Study objectives
There is no clinically significant difference between the post-operative analgesic effects of paracetamol when given orally as a pre-medication one hour pre-operatively, and when given as an intravenous infusion immediately pre-operatively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brighton East Research Ethics Committee approved as of 19th February 2008 (ref: 08/H1107/16)

Study design
Randomised, controlled, blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Analgesia in wisdom tooth extraction

Interventions
Participants will be randomly assigned to either:
1. Oral pre-med group: two 500 milligram paracetamol capsules and 100 ml bag of normal saline for injection, or
2. IV group: two placebo lactose capsules and 100 ml (1 gram) of paracetamol for injection

The oral pre-medication will be given one hour prior to surgery and the intravenous whilst the participant is under a general anaesthetic. Duration of treatment 15 minutes for intravenous injection. Duration of follow up until discharged from hospital (max 3 - 4 hours).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Paracetamol

Primary outcome measure
We will compare the pain scores of patients in the two study arms one hour post-operatively. This will be done in recovery using a Visual Analogue Scale (VAS) pain scoring system.

Secondary outcome measures
We will compare the time to request of post-operative rescue analgesia between the two study arms. Specifically, this will be measured from when the patient arrives in recovery. This point will serve as a standard time zero (t0). The time elapsed before the patient requests additional analgesia (if at all) will act as a secondary surrogate marker of analgesic efficacy.

Overall study start date
31/03/2008

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Patients over 18 years (either sex) having a general anaesthetic for extraction of wisdom teeth of which at least one must be a lower molar tooth.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
116

Key exclusion criteria
1. Patients who are unable to give full consent, or who do not wish to take part in the trial
2. Patients who have a baseline Visual Analogue Scale (VAS) score of more than zero
3. Patients unable to swallow tablets

4. Patients who have taken simple analgesics that day, prior to surgery
5. Hypersensitivity or history of serious adverse reactions to paracetamol or non-steroidal anti-inflammatory drugs
6. Active liver disease
7. Renal dysfunction
8. Pregnant or breast feeding women
9. Alcohol or drug abuse
10. History of unresponsiveness to paracetamol
11. Gastric or peptic ulcer disease
12. Inflammatory bowel disease
13. Blood coagulation abnormalities

Date of first enrolment
31/03/2008

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Victoria Hospital NHS Foundation Trust
East Grinstead
United Kingdom
RH19 3QE

Sponsor information

Organisation
Queen Victoria Hospital NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.qvh.nhs.uk/

ROR
https://ror.org/03bs2yy11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (UK) - the Research for Patient Benefit (RfPB) programme

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/03/2013		Yes	No