

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

|                                        |                                                   |                                                      |
|----------------------------------------|---------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>22/01/2008   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>09/05/2008 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>12/12/2012       | <b>Condition category</b><br>Signs and Symptoms   | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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(s)**

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.

### **Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

### **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)

### **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**

### **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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/03/2013   |            | Yes            | No              |