

# Analgesia provided by intravenous paracetamol compared with intravenous morphine, for pain secondary to isolated limb trauma, in the emergency department: a pilot randomised trial

<b>Submission date</b> 16/06/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/03/2012	<b>Condition category</b> 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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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

2188

# Study information

## Scientific Title

## Study objectives

Analgnesia provided by paracetamol is equivalent to that provided by morphine.

Added as of 31/12/2008: This trial has completed recruitment, data analysis ongoing.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

North Somerset and South Bristol Research Ethics Committee, approved on 09/08/2007 (ref: 07 /H0106/118)

## Study design

Double-blind randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Quality of life

## 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

Isolated limb trauma

## Interventions

Intravenous paracetamol (1 g) or intravenous morphine (10 mg).

## Intervention Type

Drug

## Phase

Phase IV

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

Paracetamol , morphine

**Primary outcome measure**

Visual analogue pain score, measured at 0, 5, 15, 30 and 60 minutes (the drug infusion starts at time 0).

**Secondary outcome measures**

1. Requirement for rescue morphine
2. Patient satisfaction of overall analgesia on five point likert scale at 60 minutes
3. Occurrence of side effects

**Overall study start date**

01/09/2007

**Completion date**

01/09/2008

**Eligibility****Key inclusion criteria**

1. Isolated limb trauma
2. Moderate to severe pain, with initial verbal pain score of 7 or more
3. Age >15 and <65 years
4. Weight >50 kg

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

60

**Key exclusion criteria**

1. Chest pain
2. Glasgow Coma Scale (GCS) <15
3. Allergy to morphine or paracetamol
4. Known liver disease, or patient clinically jaundiced
5. Major Trauma
6. Known pregnancy
7. Breast feeding
8. Patients requiring an immediate limb-saving procedure
9. Age <16 or >65 years

- 10. Patients in extreme distress who are unable to consent
- 11. Communication difficulties (foreign language, prior confusion) preventing informed consent or co-operation with pain scoring

**Date of first enrolment**

01/09/2007

**Date of final enrolment**

01/09/2008

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Emergency Department**

Bristol

United Kingdom

BS2 8HW

## **Sponsor information**

**Organisation**

United Bristol Healthcare NHS Trust (UK)

**Sponsor details**

Marlborough Street

Bristol

England

United Kingdom

BS2 8HW

+44 (0)117928 3473

maria.palmer@ubht.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.ubht.nhs.uk/>

**ROR**

<https://ror.org/04nm1cv11>

# Funder(s)

## Funder type

University/education

## Funder Name

College of Emergency Medicine (UK)

## Alternative Name(s)

CEM

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## Location

United Kingdom

# 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?
<a href="#">Results article</a>	results	01/01/2012		Yes	No