

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

Submission date 16/06/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 29/08/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/03/2012	Condition category Signs and Symptoms	☐ 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

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)

Primary study design

Interventional

Study design

Double-blind randomised controlled trial

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Emergency Department

Bristol

United Kingdom

BS2 8HW

Sponsor information

Organisation

United Bristol Healthcare NHS Trust (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

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	01/01/2012		Yes	No