ISRCTN52451941 https://doi.org/10.1186/ISRCTN52451941

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

Registration date
29/08/2007

Overall study status
Completed

Last Edited
29/03/2012

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Anaglesia 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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes