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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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. Occurence 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?
Results article	results	01/01/2012		Yes	No