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A blinded randomised controlled trial to assess rapidity, effectiveness, acceptability and safety with intranasal diamorphine compared to oral morphine of analgesia

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
05/12/2014

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
N0206102394

Study information

Scientific Title
A blinded randomised controlled trial to assess rapidity, effectiveness, acceptability and safety with intranasal diamorphine compared to oral morphine of analgesia

Study objectives
In children aged between 4-16 years attending Accident and Emergency (A&E) with acute traumatic injury, is there an improvement in safety, speed of onset and efficacy of analgesia, and patient acceptability using intranasal diamorphine compared to Oramorph?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-blinded double dummy randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
Intranasal diamorphine vs oral morphine

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Diamorphine, morphine

Primary outcome measure
Time to onset of analgesia and efficacy of analgesia.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2002

Completion date
31/03/2005

Eligibility

Key inclusion criteria
1. Children aged 4-16 years attending the Accident and Emergency (A&E) department
2. With an acute injury who do not need resuscitation
3. Who would normally be offered oral morphine for analgesia

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
150 subjects in each arm

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2002

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool Children's Hospital NHS Trust
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Liverpool Children's NHS Trust (UK)

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