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	Prospectively registered
		Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
05/12/2014	Signs and Symptoms	Record updated in last year

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

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