Analgesia in acute injury

Submission date	Recruitment status	Prospectively registered		
30/09/2004	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2004	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
03/08/2012	Injury, Occupational Diseases, Poisoning			

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

N0013129667

Study information

Scientific Title

Study objectives

The study is designed to decide whether the COX-2 specific non-steroidal anti-inflammatory drug rofecoxib is effective in the relief of pain in patients with acute upper and lower limb injuries.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Pain, lower leg injury

Interventions

Patients will be randomised to receive either rofecoxib or diclofenac at the triage area. They will have regular objective and subjective pain and functional assessments and will be treated in the department (as per normal). They will receive the study drugs for a further 5 days, with ongoing assessments.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The main outcome measure is the change in VAS score over time after the initial dose of study medication over the next 4 hours.

Secondary outcome measures

Secondary outcome measures are twice daily patient's global assessments of pain and VAS score. There will be a modified SF-36 to complete on day 5.

Overall study start date

19/06/2003

Completion date

19/12/2003

Eligibility

Key inclusion criteria

Patients presenting to the emergency department with acute lower limb injuries. These must be less than 48 hours old and only include non-penetrating injuries with a pain score of 40 mm or more on a 100 mm Visual Analogue Scale (VAS).

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

19/06/2003

Date of final enrolment

19/12/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Oral Medicine Department London United Kingdom SE1 9RT

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Guy's and St Thomas' 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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Abstract results	results in 'Leading Abstracts of the Third Mediterranean Emergency Medicine Congress, Nice, France; September 1-5 2005'	01/02 /2006		No	No