ISRCTN21732767 https://doi.org/10.1186/ISRCTN21732767

Analgesia in acute injury

Submission date	Recruitment status
30/09/2004	No longer recruiting
Registration date	**Overall study status**
30/09/2004	Completed
Last Edited	**Condition category**
03/08/2012	Injury, Occupational Diseases, Poisoning

[_] 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
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

Study type(s)
Other

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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's and St Thomas' NHS Trust (UK)

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?
Abstract results	results in 'Leading Abstracts of the Third Mediterranean Emergency Medicine Congress, Nice, France; September 1-5 2005'	01/02/2006		No	No