

Analgesia in acute injury

Submission date

30/09/2004

Recruitment status

No longer recruiting

Registration date

30/09/2004

Overall study status

Completed

Last Edited

03/08/2012

Condition category

Injury, Occupational Diseases, Poisoning

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ 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

Primary study design

Interventional

Study design

Randomised controlled trial

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