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

# 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

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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 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 |