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A clinical trial of Hamilton-Russell traction on a) incidence of pressure sores, and b) pre-operative pain, in patients with fractured neck of femur.

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
11/01/2010

Condition category
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ACLINIC

Study information

Scientific Title

Study objectives
We propose to evaluate the effect of Hamilton-Russell traction on (a) the peri-operative incidence of pressure sores and (b) pre-operative pain, in patients with fractured neck of femur. There is little evidence to suggest that traction confers any advantage in the pre-operative period, upon patients who receive it. Furthermore, its use may increase the risk of pressure sore development. If the data from the study supports the hypothesis that Hamilton-Russell traction has no beneficial effect, we can strongly argue for its discontinuation. Money currently spent on traction kits will be saved. Furthermore, patient suffering will be reduced through a reduction in the development of pressure sores.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal injury

Interventions
Application of Hamilton-Russell traction

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Pain (measured by Bourbonnais pain ruler, a visual analogue scale)
2. Pressure sore (Torrance 5 point scale)

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/01/1993

Completion date
30/09/1995

Eligibility

Key inclusion criteria
1. Fractured neck of femur deemed suitable for surgical fixation
2. Patient Consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
303 (added 11/01/10, see publication)

Key exclusion criteria
1. Multiple fractures or injuries
2. Pressure sores
3. Absence, paralysis or fracture of lower limb

Date of first enrolment
10/01/1993

Date of final enrolment
30/09/1995

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Hull
Hull
United Kingdom
HU6 7RX

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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?
Results article		01/12/1997		Yes	No