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A multicentre randomised controlled study of primary femoral fixation versus delayed definitive femoral fixation in patients with multiple trauma

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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/08/2016	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

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
N0436125527

Study information

Scientific Title
A multicentre randomised controlled study of primary femoral fixation versus delayed definitive femoral fixation in patients with multiple trauma

Study objectives
This study aims to compare the effects of early primary intramedullary nailing and delayed femoral intramedullary nailing in patients who have sustained a femoral shaft fracture and multiple injuries with an injury severity score of >16. It will be in particular studying the rates of complications such as multi-organ failure and acute respiratory distress syndrome to see if there is a difference in the incidence of these between the two techniques.

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
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Injury, Occupational Diseases, Poisoning: Femoral shaft fracture

Interventions
Randomised controlled trial

Intervention Type

Procedure/Surgery

Primary outcome measure
Mean ventilation

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2002

Completion date
01/08/2003

Eligibility

Key inclusion criteria
10-20 patients who have sustained polytrauma

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
20

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/08/2002

Date of final enrolment
01/08/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

St James's University Hospital
Leeds
United Kingdom
LS9 7TF

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
Leeds Teaching Hospitals 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