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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

Protocol serial number
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

Study type(s)
Treatment

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

Interventions
Randomised controlled trial

Intervention Type
Procedure/Surgery

Primary outcome(s)
Mean ventilation

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/08/2003

Eligibility

Key inclusion criteria

10-20 patients who have sustained polytrauma

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
01/08/2002

Date of final enrolment
01/08/2003

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes