

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

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 02/08/2016	Condition category Injury, Occupational Diseases, Poisoning	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Primary study design

Interventional

Study design

Randomised controlled trial

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