

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/08/2016	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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