# 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
		☐ 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

#### Contact name

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#### Contact details

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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