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Is a neutralisation plate always necessary in the treatment of unstable ankle fractures?

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
16/12/2014	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
N0034136470

Study information

Scientific Title

Is a neutralisation plate always necessary in the treatment of unstable ankle fractures?

Study objectives
To ascertain whether the avoidance of a plate will minimise soft tissue problems and lateral hardware associated pain and hence reduce the need for the removal of metalwork whilst maintaining adequate fracture fixation

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

Health condition(s) or problem(s) studied
Injury, Occupational Diseases, Poisoning: Ankle fractures

Interventions
Neutralisation plate vs standard practice

Intervention Type
Procedure/Surgery

Primary outcome measure
Efficacy of treatment

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2002

Completion date
01/04/2005

Eligibility

Key inclusion criteria
All adults over 18 years of age admitted to this Trust will be randomised.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2002

Date of final enrolment
01/04/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barnsley Hospital
Barnsley
United Kingdom
S75 2EP

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
Barnsley District General Hospital 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