

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

Submission date

30/09/2004

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

30/09/2004

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

16/12/2014

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Jonathan McGregor-Riley

Contact details

Barnsley Hospital

Barnsley

United Kingdom

S75 2EP

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