

AS04 Ankle study of fracture treatment in the older patient

Submission date 23/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/07/2016	Condition category Injury, Occupational Diseases, Poisoning	<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

Ms Bridget Gray

Contact details

Kadoorie Centre for Critical Care Research
Level 3, Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

7109

Study information

Scientific Title

Influence of ankle skin perfusion on fracture treatment outcomes in the elderly: a randomised controlled trial comparing total contact cast with open reduction and internal fixation, the effect on cutaneous blood supply and relationship to skin complications

Acronym

AS04 Ankle study

Study objectives

Current proven treatment methods for ankle fracture in the older patient can be associated with complications due to poor skin, bone or healing. A casting technique, proven successful in treating critical skin breakdown in diabetic patients, has in a local audit shown potential as an alternative treatment in the elderly ankle fracture patient. This study will address the questions:

1. What contribution does the adequacy of the skin blood supply make to healing
2. How does a new cast treatment compare with the 'traditional' open surgical approach with regard to healing and function

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxfordshire Research Ethics Committee approved on the 1st August 2003 (ref: C03 071)

Study design

Randomised interventional 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Injuries and Accidents; Subtopic: Injuries and Accidents (all Subtopics); Disease: Injuries & Accidents

Interventions

Group A (comparator): ORIF -

Patients will be anaesthetised and have a surgical open reduction and internal fixation by a contemporary method using metal plates and screws.

Group B (intervention): Close Contact Cast -

Patients will be anaesthetised and undergo closed manipulation of the fracture, and then application of a close contact cast.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Functional outcome at 6 months - using the Olerud and Molander Ankle Score - a self reported score

Secondary outcome measures

Skin complications, radiological assessment, quality of life at 6 weeks and 6 months.

Overall study start date

01/05/2004

Completion date

31/07/2010

Eligibility

Key inclusion criteria

1. Unstable ankle fracture
2. Aged over 60 years, either sex

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria

1. Open fractures
2. Multiple injuries
3. Type 1 diabetes
4. Active leg ulceration
5. Critical leg ischaemia
6. Unfit for anaesthesia

Date of first enrolment

01/05/2004

Date of final enrolment

31/07/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Kadoorie Centre for Critical Care Research

Oxford

United Kingdom

OX3 9DU

Sponsor information

Organisation

Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details

Research and Development Department

John Radcliffe Hospital

Headley Way

Headington

Oxford

England

United Kingdom

OX3 9DU

Sponsor type

Hospital/treatment centre

Website

<http://www.oxfordradcliffe.nhs.uk/home.aspx>

ROR

<https://ror.org/03h2bh287>

Funder(s)

Funder type

Research organisation

Funder Name

AO Research Foundation (Switzerland)

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