

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
Registration date 23/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/07/2016	Condition category 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
Ms Bridget Gray

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

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

31/07/2010

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

Study participating centre

Kadoorie Centre for Critical Care Research
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation

Oxford Radcliffe Hospitals NHS Trust (UK)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

AO Research Foundation (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration