

# AS04 Ankle study of fracture treatment in the older patient

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

### 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes