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Comparison of close contact cast (CCC) technique to open surgical reduction and internal fixation (ORIF) in the treatment of unstable ankle fractures in patients over 60 years

Submission date	Recruitment status
29/04/2009	No longer recruiting
Registration date	**Overall study status**
08/05/2009	Completed
Last Edited	**Condition category**
26/07/2019	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
25% of ankle fracture patients are over the age of 60. The proven treatments suitable in young patients are not necessarily appropriate in later life. The ankle bones, leg circulation and skin quality all become more fragile with age. To achieve the best result in treating ankle fractures, the key objective must be to ensure the bones around the ankle joint heal in the best position to maintain function. For most patients, this requires an operation to set the bones back into position by inserting a metal plate and screws. However, some patients may be treated by manipulating the bones back into position under anaesthesia and then applying a close contact cast, which is a standard plaster cast applied by a specialised technique. Both of these treatments have advantages and disadvantages for older patients. The plates and screws are good at holding the exact position but can fail if the bone is weak or if the surgical wound does not heal or becomes infected. The alternative, manipulation and a plaster cast, has been found to be less good at holding the position in some people. It can also cause skin problems from the pressure of the plaster. In the past, most patients have been treated with plate and screw surgery. However, a plaster cast technique developed to treat diabetic patients has now been successfully modified for use in older patients with unstable ankle fractures. The aim of this study is to determine whether this modified cast treatment using a 'close contact cast' is equivalent to the operation using plates and screws, i.e. it gives the same results without the need for open surgery and the risks of wound healing problems and infection.

Who can participate?
Patients aged over 60 with an ankle fracture

What does the study involve?
Participants are randomly allocated to be treated with either the close contact cast technique or with the standard treatment of open surgery. We then assess the healing of the bone and skin,

how well the ankle moves, and how well the patients are managing overall at 6 months after the injury.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
John Radcliffe Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2009 to October 2014

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof. Keith Willett

Contact information

Type(s)
Scientific

Contact name
Prof Keith Willett

Contact details
Kadoorie Centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 07/37/61

Study information

Scientific Title
Comparison of close contact cast (CCC) technique to open surgical reduction and internal fixation (ORIF) in the treatment of unstable ankle fractures in patients over 60 years: a pragmatic randomised controlled equivalence study

Acronym
AIM (Ankle Injury Management)

Study objectives
Primary research objective
To determine if the application of the close contact casting technique (CCC) for displaced ankle fractures in older adults results in an equivalent outcome compared to the standard care of open surgical internal fixation (ORIF) in terms of function, complications, quality of life and patient satisfaction with treatment.

Secondary research objective
An economic evaluation will run in parallel to the trial and will consider the costs of the two treatments to (i) the NHS, and (ii) the broader societal perspective including to the individual and their family.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire Research Ethics Committee A, ref: C03.071

Original approval: 03/09/2003
Substantial amendment approval: 18/08/2008

Study design
Multi-centre pragmatic individually randomised controlled equivalence study

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Displaced unstable fracture of the ankle

Interventions
Participants will be randomised to receive ORIF or CCC.

Standard care group - ORIF:
Specific implant selection will not be fixed by the trial but surgeons must comply with the (universally used) implant designs and concept of ankle fracture fragment reduction and fixation techniques. These specifications recognise historically proven concepts for successful internal fixation - AO Principles of Fracture Management .

Intervention group - CCC:
Standardisation of the casting materials, cast design and application, and moulding technique will exist by surgeon instruction and information documentation. The method of closed fracture manipulative reduction of deformity will be left to individual surgeons and this falls within the common contemporary skills set of senior surgical trainees and consultants.

All cases will conform to the NHS standard of being performed under consultant supervision and rehabilitation guidance will be the same for both treatment groups once bone healing has been confirmed as suitable to commence weight-bearing.

Intervention Type
Procedure/Surgery

Primary outcome measure
Patient reported functional outcome measure based on the Olerud and Molander Ankle Score. This scores 10 separate activities:
Pain, stiffness, swelling, jumping, supports, activities of daily living, running, stair climbing and squatting with a range of 0 to 100.

Some of the items may not be relevant or sensitive to change in the older patient, including running, squatting and jumping so it will be analysed at each individual item level. If there is evidence of a significant floor effect these items will be excluded from the final analysis and be summarised as a modified Olerud and Molander Score.

All primary outcomes will be assessed at baseline, 6 weeks and 6 months.

Secondary outcome measures
10 days post ORIF:
1. ASEPSIS wound score - to assess soft tissue complications including wound edge necrosis and infection with range of 0 to 70 (under 10 = normal healing)

6 weeks:
1. Iowa ankle score: ankle range of movement component - goniometer measurement in flexion, extension, inversion and eversion
2. Radiological measurements of fracture and ankle joint congruence
3. Euroqol EQ-5D and SF-12® Health Survey - Quality of life/utilities measure
4. Patient satisfaction measure - tailored questionnaire
5. Qualitative assessment by semi-structured interview of a 20 participant sample each group

6 months:
1. Iowa ankle score - ankle range of movement component: goniometer measurement in flexion, extension, inversion and eversion
2. Radiological measurements of fracture and ankle joint congruence
3. Euroqol EQ-5D and SF-12® Health Survey - Quality of life/utilities measure
4. Patient satisfaction measure - tailored questionnaire

5. Timed 'Get up and Go' test
6. Cost-effectiveness will be measured by an economic analysis conducted along side the trial and will include modelling to extrapolate beyond trial data to give cost per Quality-Adjusted Life Years (QALY) estimates. The analysis will incorporate the elements of:
6.1. Duration of inpatient hospital stay
6.2. Theatre time/implant costs
6.3. Fracture Clinic visits
6.4. Additional treatment costs and
6.5. Social dependency/support change at 6 months

Overall study start date
01/10/2009

Completion date
01/10/2014

Eligibility

Key inclusion criteria
1. Men or women aged over 60 years
2. Isolated displaced unstable ankle fracture
3. Ambulatory prior to the injury - in any capacity
4. Capable of giving informed consent
5. Capable of adhering to post-operative instructions
6. Resident within the catchment area of a recruiting hospital - can attend for 6 month follow up

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
620

Key exclusion criteria
1. Established critical limb ischaemia
2. Insulin dependent diabetes
3. Active leg ulceration
4. Open fractures
5. Serious contaminant disease - metastatic disease or terminal illness
6. Clinically substantial degenerative or inflammatory arthritis
7. Unfit for anaesthetic
8. Unable to give informed consent - cognitive impairment demonstrated by Mini-Mental State Exam (MMSE) of under 16/30
9. Patient unwilling to give informed consent

Date of first enrolment
01/10/2009

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials and Research Governance
Manor House
John Radcliffe Hospital
Headington
Oxford
England
United Kingdom
OX3 9DZ

Sponsor type
University/education

Website
http://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/06/2016

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?
Protocol article	protocol	12/03/2014		Yes	No
Results article	results	01/10/2016		Yes	No
Results article	results	11/10/2016		Yes	No
Results article	results	23/07/2019	26/07/2019	Yes	No