External frame versus internal locking plate for articular pilon fracture fixation

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
26/02/2018		[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
06/03/2018		☐ Results		
Last Edited		Individual participant data		
01/10/2024	Injury, Occupational Diseases, Poisoning	[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

A pilon fracture is a severe break of the shin bone where it forms the ankle joint. It is usually caused by a high-energy impact such as a fall from a height. These injuries are very difficult to treat, and can have a very large negative effect on a person's quality of life. Surgery is needed to fix the broken bone, which can lead to serious infections, meaning more treatment is needed, including on occasion amputation. Even where the fracture heals well, most patients develop arthritis in the joint. The injury is usually fixed by orthopaedic surgeons from the inside (under the skin) using a plate and screws (internal fixation) or fixed from the outside using a ring frame or cage (external fixation). The internal plate is cheaper than the external ring but the internal plate may increase the chance of the patient getting a deep infection. There is genuine uncertainty among surgeons as to which is the preferred surgical option. National Institute for Health and Care Excellence and Consultant Orthopaedic Surgeons have recommended that high-quality research is needed to find out whether internal or external fixation is best for treating pilon fractures and which is the better use of NHS money. This study aims to investigate the clinical and cost-effectiveness of internal plate fixation versus external fine wire fixation for the management of Type C pilon fractures.

Who can participate?

Patients aged 16 or older with a closed type C pilon fracture of the tibia

What does the study involve?

Participants are randomly allocated to undergo either internal plate fixation or external fine wire fixation. All participants receive standardised, written physiotherapy advice detailing the exercises they need to perform for rehabilitation following their injury. They are advised to move their toes, ankle and knee joints fully within the limits of their comfort. Early weight-bearing is encouraged, but the details are decided by the treating surgeon. Any other rehabilitation input including and beyond written physiotherapy advice (such as formal referral to physiotherapy) is left to the discretion of the treating clinicians. The participants' own ratings of their disability are collected at 3, 6, 12 and 24 months follow-up.

What are the possible benefits and risks of participating?
As there is uncertainty regarding which treatment is best, there is no specific benefit to the

participants other than the potential to inform future clinical practice and to help future patients decide which treatment is best for them. Both study treatments are used in routine NHS practice, so no new risks are anticipated beyond those that are already associated with the treatments used.

Where is the study run from? Hull Royal Infirmary (UK)

When is the study starting and how long is it expected to run for? September 2017 to April 2025

Who is funding the study? National Institute for Health Research (NIHR) (UK)

Who is the main contact?

- 1. Stephen Brealey
- 2. Hemant Sharma

Study website

https://www.journalslibrary.nihr.ac.uk/programmes/hta/1513084

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

224065

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 36103, HTA 15/130/84, IRAS 224065

Study information

Scientific Title

External frame versus internal locking plate for articular pilon fracture fixation: a multi-centre randomised controlled trial

Acronym

ACTIVE

Study objectives

This study aims to investigate the clinical and cost-effectiveness of internal plate fixation versus external fine wire fixation for the management of Type C pilon fractures.

Ethics approval required

Ethics approval required

Ethics approval(s)

- 1. Approved 13/02/2018, Yorkshire & The Humber Bradford Leeds Research Ethics Committee (Jarrow Business Centre, Jarrow, NE32 3DT, United Kingdom; +44 (0)207 104 8081; bradfordleeds.rec@hra.nhs.uk), ref: 18/YH/0014
- 2. Approved 02/03/2022, University of Cape Town, Faculty of Health Sciences, HREC (E53-Room 46, Old Main Building, Groote Schurr Hospital, Cape Town, Observatory 7925, South Africa; None available; hrec-enquiries@uct.ac.za), ref: 700/2021

3. Approved 23/04/2021, Sydney Local Health District Research Ethics and Governance Office (Research Ethics and Governance Office, Royal Prince Alfred Hospital, Camperdown, NSW 2050, Australia; +61 020 9515 7035; SLDH-RPAEthics@health.nsw.gov.au), ref: X21-0041 & 2020 /ETH02046

Study design

Randomized controlled 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 to request a patient information sheet

Health condition(s) or problem(s) studied

Injuries to the knee and lower leg

Interventions

Participants will be randomly allocated into one of two techniques for the operative fixation of closed type C pilon fractures:

Internal plate fixation

The 'locking' plate is inserted at the distal end of the tibia and passed under the skin on the surface of the bone. The details of the reduction technique, the surgical approach, the type and position of the plate, the number and configuration of fixed-angle screws and any supplementary device or technique will be left to the discretion of the surgeon. The only stipulation is that fixed angle screws must be used in at least some of the distal screw holes as this is standard practice with all distal tibia 'locking' plates.

External frame fixation

A limited minimally invasive open reduction and fixation of articular segment is undertaken. Once the articular segment is stabilized, the circular fixator is applied to the bone. Incision site, number and configuration of screws, number of rings, wires and half pins will depend on the fracture configuration and will be left at the discretion of the surgeon. Occasionally, synthetic /iliac crest bone grafts may be necessary and circular fixator will have to extend across the ankle, which again will be left at the discretion of surgeon.

Post-surgery rehabilitation

All patients randomised into the two groups will receive standardised, written physiotherapy advice detailing the exercises they need to perform for rehabilitation following their injury.

Patients in both groups will be advised to move their toes, ankle and knee joints fully within the limits of their comfort. Early weight-bearing will be encouraged, but the details of weight-bearing status will be decided by the treating surgeon. In this pragmatic trial, any other rehabilitation input including and beyond written physiotherapy advice (such as formal referral to physiotherapy) will be left to the discretion of the treating clinicians.

Patient reported outcome measures at baseline, 3, 6, 12 and 24 months after randomisation.

Intervention Type

Procedure/Surgery

Primary outcome measure

Patient's own rating of their disability specifically related to the lower limb, assessed using the Disability Rating Index (DRI) at baseline, 3, 6, 12 and 24 months follow-up post-randomisation. The DRI is a validated patient-reported outcome measure questionnaire. It consists of a 12-item Visual Analogue Scale questionnaire. The DRI has been proven to be a robust, practical clinical and research instrument with good responsiveness and acceptability for assessment of disability caused by impairment in the lower limb. The baseline assessment will ask participants about their functioning before their injury and before their surgery. Twelve months after randomisation has been chosen to be the primary endpoint to allow the interventions and co treatment interventions to be delivered and the majority of complications to be treated.

Secondary outcome measures

- 1. Olerud and Molander Ankle Score (OMAS) collected at baseline, 3, 6, 12 and 24 months follow-up
- 2. Patient health related quality of life, assessed using the EQ5D-5L generic and health economic self-complete patient-reported outcome measure. This will be collected twice at baseline: i.e. once to assess patient health related quality of life on the day (after the injury) and once with regard to patient health related quality of life during the week before injury; then once each at 3, 6, 12 and 24 months
- 3. Complications: Data on all further surgical procedures and other complications, e.g. deep wound infection (using Centres for Disease Control and Prevention definition), superficial infection, pin site infection (defined using the 'Good, Bad and Ugly' pin site grading system), rehospitalisation, blood clots, wound dehiscence, septic arthritis, secondary interventions for non-union and all other secondary procedures will be collected at 3, 6, 12 and 24 months
- 4. Non-union, mal-union and secondary arthritis. Non-union will be defined as inability to heal as confirmed on x rays/CT scan or as secondary intervention for failure to heal. Mal-union is defined by a standard measurement based on Dror Paley's technique, undertaken using final radiographs at 12 months. Secondary arthritis in the ankle will be assessed using the Kellgren and Laurence scale
- 5. Resource use and work impact: Data on resource use and work impact will be collected to inform the economic evaluation (e.g. length of hospital stay, rehospitalisation and return to work). This data will be gathered at 3, 6, 12 and 24 months
- 6. Patient preference for treatment: Data on patient preferences will be collected at baseline and 12 months
- 7. Transition question: To assist interpretation of findings, patients will be asked at the 12-month follow-up time-point whether compared with when they initially sustained the pilon fracture one year previously, how their ankle is currently

Overall study start date

01/09/2017

Completion date

31/10/2024

Eligibility

Key inclusion criteria

Current inclusion criteria as of 05/03/2019:

- 1. Patients aged 16 years or older
- 2. With a closed intraarticular pilon fracture of the distal tibia classified according to AO: AO 43 C1, C2 and C3 (complete articular). This includes patients with a bi-lateral pilon fracture and who have polytrauma.
- 3. Where the treating surgeon believes the patient will benefit from surgical fixation

Previous inclusion criteria:

- 1. Patients aged 16 years or older
- 2. With a closed unilateral intraarticular pilon fracture of the distal tibia classified according to AO: AO 43 C1, C2 and C3 (complete articular). Only unilateral fractures are included since problems may occur in rehabilitation with bilateral fractures which may compromise outcomes 3. Where the treating surgeon believes the patient will benefit from surgical fixation

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

Planned Sample Size: 250; UK Sample Size: 250

Total final enrolment

255

Key exclusion criteria

- 1. More than 21 days since injury
- 2. Previous failed fixation
- 3. Pathologic fracture
- 4. Pre-existing (pre-injury) skin condition which precludes open surgery
- 5. Patient is/would be unable to understand instructions for treatment

Date of first enrolment

09/03/2018

Date of final enrolment

31/10/2023

Locations

Countries of recruitment

Australia

England

Northern Ireland

Scotland

South Africa

United Kingdom

Wales

Study participating centre Hull Royal Infirmary (lead centre)

Hull United Kingdom HU3 2JZ

Study participating centre John Radcliffe Hospital

Headley Way Headington Oxford United Kingdom OX3 9DU

Study participating centre Royal Liverpool University Hospital

Prescot Street Liverpool United Kingdom L7 8XP

Study participating centre St Georges University Hospitals NHS Foundation Trust

Blackshaw Road Tooting London United Kingdom SW17 0QT

Study participating centre The Royal London Hospital

Barts Health NHS Trust Whitechapel Road London United Kingdom E1 1BB

Study participating centre Royal Cornwall Hospitals NHS Trust

Treliske Truro United Kingdom TR1 3LQ

Study participating centre Poole Hospital NHS Foundation Trust

Longfleet Road Poole United Kingdom BH15 2JB

Study participating centre Nottingham University Hospitals NHS Trust

Hucknall Rd Nottingham United Kingdom NG5 1PB

Study participating centre Sheffield Teaching Hospitals NHS Foundation Trust

Herries Road Sheffield United Kingdom S5 7AU

Study participating centre South Tees Hospitals NHS Foundation Trust

Middlesbrough United Kingdom TS4 3BW

Study participating centre Royal Stoke University Hospital

Newcastle Road Stoke-on-Trent United Kingdom ST4 6QG

Study participating centre Royal Berkshire NHS Foundation Trust

London Road Reading United Kingdom RG1 5AN

Study participating centre

Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust

Gobowen Oswestry United Kingdom SY10 7AG

Study participating centre Norfolk and Norwich University Hospital NHS Foundation Trust

Colney Lane Norwich United Kingdom NR4 7UY

Study participating centre

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Armthorpe Road Doncaster United Kingdom DN2 5LT

Study participating centre University Hospital Southampton NHS Foundation Trust

Tremona Road Southampton United Kingdom SO16 6YD

Study participating centre Queen Elizabeth Hospital

Mindelsohn Way Edgbaston Birmingham United Kingdom B15 2TH

Study participating centre Taunton and Somerset NHS Foundation Trust

Parkfield Drive Taunton United Kingdom TA1 5DA

Study participating centre Morriston Hospital

Port Talbot Swansea United Kingdom SA12 7BR

Study participating centre Wythenshawe Hospital

Manchester University NHS Foundation Trust Oxford Road Manchester United Kingdom M13 9WL

Study participating centre

Leeds General Infirmary

Great George Street Leeds United Kingdom LS1 3EX

Study participating centre King's College NHS Foundation Trust London United Kingdom SE5 9RS

Study participating centre
University Hospitals Leicester NHS Foundation Trust
Leicester
United Kingdom
LE1 5WW

Study participating centre Imperial College Healthcare NHS Trust London United Kingdom W2 1NY

Study participating centre Queen Elizabeth University Hospital Glasgow United Kingdom G51 4TF

Study participating centre Glasgow Royal Infirmary Glasgow United Kingdom G4 0SF

Study participating centre Royal Derby Hospital Derby United Kingdom DE22 3NE

Study participating centre Aberdeen Royal Infirmary Aberdeen United Kingdom AB25 2ZN

Study participating centre
Durham and Darlington NHS Trust
Darlington
United Kingdom
DL3 6HX

Study participating centre Altnagelvin Area Hospital Londonderry United Kingdom BT47 6SB

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
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United Kingdom
CV2 2DX

Study participating centre Groote Schuur Hospital Anzio Road, Observatory Cape Town South Africa SA 7925

Study participating centre St George HospitalGray Street

Kogarah Sydney Australia NSW 2217

Study participating centre The Sutherland Hospital

Kareena Road Caringbah Sydney Australia NSW 2229

Study participating centre Liverpool Hospital

75 Elizabeth Street Liverpool Sydney Australia NSW 2170

Study participating centre Fiona Stanley Hospital

11 Robin Warren Drive Murdoch Perth Australia WA 6150

Study participating centre John Hunter Hospital

Lookout Road New Lambton Heights Sydney Australia NSW 2305

Sponsor information

Organisation

Hull and East Yorkshire Hospitals NHS Trust

Sponsor details

Research and Development Department Castle Hill Hospital Cottingham Hull England United Kingdom HU16 5JQ

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/01b11x021

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 15/130/84

Results and Publications

Publication and dissemination plan

Additional documentation will be added to the NIHR website when available: https://www.journalslibrary.nihr.ac.uk/programmes/hta/1513084/#/

The trialists plan to disseminate trial results to key stakeholders and patients in several ways:

- 1. The study protocol will be published in a peer-reviewed, open access journal
- 2. A HTA research monograph will be produced
- 3. In conjunction with patient members of the team they will generate patient information for "Shared Decision Making" based on findings from this trial and update the entry on Wikipedia and write the Map of Medicine entry on pilon fractures management
- 4. The results of the study will be presented at national and international surgical meetings such as the British Orthopaedic Association Annual Congress, the UK Orthopaedic Trauma Society meeting, the North American Orthopaedic Trauma Association the European Federation of National Associations of Orthopaedics and Traumatology (EFFORT), Société Internationale de Chirurgie Orthopédique et de Traumatologie (SICOT and the American Academy of Orthopaedic Surgeons
- 5. The findings will be published in peer reviewed high impact general medical and orthopaedic journals such as Lancet, the BMJ or similar
- 6. A summary of the study report, written in lay language will be produced and made available to

participants, members of the user group and relevant patient-focused websites A full dissemination strategy will be produced for the trial.

Intention to publish date

31/10/2025

Individual participant data (IPD) sharing plan

Current IPD Sharing statement as of 01/07/2020:

The datasets generated during and/or analysed during the current study are/will be available upon request. Trial participants give informed consent that the information collected about them will be used to support other research in the future and may be shared anonymously with other researchers. All the individual participant data collected during the trial, after identification and the study protocol, SAP, informed consent form and CRFs with variables names will be available. Other documents can be requested for consideration from the team. This data will be made available immediately following the main publication of the clinical effectiveness and cost-effectiveness findings with no end date. Requests may be made by researchers who provide a methodologically sound proposal for any purpose/analysis. Proposals should be directed to the Chief Investigator at hksorth@yahoo.co.uk and will be reviewed by the trial team. To gain access, data requestors will need to complete a data request form provided by York Trials Unit and sign a data confidentiality agreement as stipulated in the trial team's publication plan.

Previous IPD Sharing statement:

The datasets generated during and/or analysed during the current study are/will be available upon request from Ms Ada Keding, trial statistician (Ada.Keding@york.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	01/03/2021	16/03/2021	Yes	No
Interim results article	Recruitment optimisation study	17/06/2021	19/07/2021	Yes	No
HRA research summary			28/06/2023	No	No