ISRCTN98152560 https://doi.org/10.1186/ISRCTN98152560

External frame versus internal locking plate for articular pilon fracture fixation

Submission date
26/02/2018

Recruitment status
No longer recruiting

Registration date
06/03/2018

Overall study status
Completed

Last Edited
01/10/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[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
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HU3 2JZ

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
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United Kingdom
OX3 9DU

Study participating centre
Royal Liverpool University Hospital
Prescot Street
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United Kingdom
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Study participating centre
St Georges University Hospitals NHS Foundation Trust
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United Kingdom
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Study participating centre
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Study participating centre
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TR1 3LQ

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BH15 2JB

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TS4 3BW

Study participating centre
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Newcastle Road
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ST4 6QG

Study participating centre
Royal Berkshire NHS Foundation Trust
London Road
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RG1 5AN

Study participating centre
Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Gobowen
Oswestry
United Kingdom
SY10 7AG

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Norfolk and Norwich University Hospital NHS Foundation Trust
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Norwich
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NR4 7UY

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B15 2TH

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TA1 5DA

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Study participating centre

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LE1 5WW

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London
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W2 1NY

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BT47 6SB

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United Kingdom
CV2 2DX

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Cape Town
South Africa
SA 7925

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St George Hospital
Gray Street

Kogarah
Sydney
Australia
NSW 2217

Study participating centre
The Sutherland Hospital
Kareena Road
Caringbah
Sydney
Australia
NSW 2229

Study participating centre
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75 Elizabeth Street
Liverpool
Sydney
Australia
NSW 2170

Study participating centre
Fiona Stanley Hospital
11 Robin Warren Drive
Murdoch
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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
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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?
Protocol article	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