

Surgical versus conservative treatment of LC1 pelvic fractures in the elderly

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| Submission date 01/04/2019 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 08/04/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 28/03/2024 | Condition category Injury, Occupational Diseases, Poisoning | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Lateral Compression type-1 (LC-1) pelvic fractures occur when older adults with weak bones fall onto their side. Researchers are trying to find new treatments to help people have better outcomes. Currently, people are encouraged to move as much as they can tolerate, as soon as possible after the injury. LC-1 fractures can be painful and some people are not able to get up and walk for weeks. This can cause additional health problems such as chest infections, urinary tract infections, pressure sores, and blood clots. Until recently the hardware (screws and plates) used in surgery did not grip well in bones with osteoporosis so surgery was rare. Pelvic surgeons now think patients may benefit from a new technique called INFIX which uses a bar and screws to stabilise the pelvis. If people are able to get moving sooner, this may help them to get back to their normal activities and save money on rehabilitation and care. However, there can be risks and complications with any surgery, or having a general anaesthetic. The aim of this study is to find out which treatment is better for patients.

Who can participate?

Patients aged over 60 from hospitals who have had an LC-1 fracture and are having difficulty walking.

What does the study involve?

Participants are randomly allocated to either receive surgery with the INFIX or standard non-surgical treatment. Participants are assessed at the start of the study, then at two weeks, six weeks, 12 weeks, six months, and some participants at one year. Participants complete a few questionnaires, a walking assessment (at 12 weeks), and have x-rays to check healing at 12 weeks. The cost of both treatments is calculated relative to its benefits to find out which is better value for money for the NHS.

What are the possible benefits and risks of participating?

Both treatment options are routinely used in the NHS to treat this type of pelvic fracture. The possible advantages of having surgery are that the break in the pelvis is stabilised, which may lead to less pain when walking and doing everyday activities. Less painful movement may mean that patients are able to return to normal activities more quickly. The possible benefits of receiving non-operative management are that patients are not exposed to any of the risks

associated with having an operation, which are discussed below. The possible risks related to surgical fixation include pain around the lower belly and stiffness in the hips. This usually improves after 48 hours or so as the body heals. After surgery there can be bleeding from the incision onto the dressing. This is continuously monitored and dressings will be changed as needed. The outside of the thigh may become numb or patients may experience a tingling sensation. If this occurs the metal work can be removed after the pelvis has healed. After surgery in the first 1-2 days some patients can experience confusion, this is related to the anaesthesia and improves over time. Rare risks include wound infection, if this were to occur it is treated with antibiotics. In rare cases of serious infection the screws and bar may need to be removed or replaced. In very rare cases there can be damage to nerves and blood vessels around the pelvis and groin. It is rare but some people can have a bad reaction to anaesthesia. There is the chance that further surgical procedures may need to be carried out for example to remove the metal work. Possible risks associated with non-operative management include rehabilitation taking longer because of ongoing pain. Usually the pain from the fracture settles down over 6-weeks or so but it can sometimes last up to 2-3 months. If the pain from the fracture prevents a patient from getting up and going, they are at risk of developing conditions such as chest and urinary infections or bed/pressure sores. Some patients can become confused, which is called delirium, after their injury, particularly if they are struggling to get up out of bed due to pain. Occasionally, fractures do not heal up fully and they require surgery, although this is a rare problem.

Where is the study run from?
Barts Health NHS Trust (UK)

When is the study starting and how long is it expected to run for?
October 2018 to December 2021

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

Who is the main contact?
Liz Cook
liz.cook@york.ac.uk

Study website
<https://www.york.ac.uk/healthsciences/research/trials/research/trials/l1>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

263397

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 41261, IRAS 263397

Study information

Scientific Title

Lateral compression type-1 fracture fixation in the elderly, a randomised controlled trial

Acronym

L1FE

Study objectives

Aim:

To investigate the clinical and cost effectiveness of surgical fixation with INFIX compared to non-surgical management of LC-1 fragility fractures in older adults.

The objectives are to:

1. Undertake a 12 month internal pilot to obtain robust estimates of recruitment and confirm trial feasibility.
2. Undertake a parallel group multi-centre randomised controlled trial to assess the effectiveness of surgical fixation with INFIX versus non-surgical management of LC-1 fragility fractures in older adults. The primary outcome is average patient quality of life and function, over the study time period, assessed by the patient-reported outcome measure, EQ-5D-5L (measured at 2 weeks, 6 weeks, 12 weeks and 6 months).
3. Undertake an economic evaluation to compare the cost-effectiveness of surgical fixation compared to non-surgical management to determine the most efficient provision of future care and to describe the resource impact on the NHS for the two treatment options.
4. Undertake a long term review of patient wellbeing (EQ-5D-5L and mortality) 12 months after entering the trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 16/07/2019, London - Harrow Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)20 71048057; nrescommittee.london-harrow@nhs.net), ref: 19/LO/0555

2. Approved for the inclusion of adults without capacity under the Adults with Incapacity (Scotland) Act 2000 12/02/2021, Scotland A Research Ethics Committee (2nd Floor Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG; +44 (0)131 465 5680; Manx.Neill@nhslothian.scot.nhs.uk), ref: 21/SS/0002

Study design

Randomised; Both; Design type: Treatment, Device, Surgery, Rehabilitation, Health Economic

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Lateral compression type-1 pelvic fracture

Interventions

Eligible and consenting patients will be randomly allocated to either surgical fixation or non-operative management.

Surgical fixation:

Surgical fixation of the pelvic fracture using INFIX, an anterior pelvic fixator device that is fitted internally. The technique involves percutaneous placement of long pedicle screws within the pelvic bone and connects them with a rod under the skin. Post-operatively, patients will receive physiotherapy as per standard of care

Non-operative management:

Standard care for LC-1 fractures in the UK is to mobilise patients as pain allows. Patients are routinely seen by a physiotherapy team, with the goals of physiotherapy to improve function, strength and range of movement in both legs, while aiming to get patients back to independent mobility as soon as possible.

Patients in both arms of the trial will also receive the standardised L1FE trial-specific, physiotherapy leaflet detailing suggested exercises to perform.

Courtesy telephone call/postcard sub-study:

The researchers will undertake an embedded randomised controlled trial to investigate the effectiveness on participant retention of making a courtesy telephone call, sending a courtesy postcard or neither within one month of participants being recruited into the L1FE trial. Participants will be randomly allocated to receive the courtesy telephone call, courtesy postcard, or no intervention. This sub-study should not represent any further burden to participants.

Intervention Type

Procedure/Surgery

Primary outcome measure

Average patient quality of life over the study time period, assessed by the patient-reported outcome measure, EuroQol 5 Dimensions (5L) utility score (EQ-5D-5L). The EQ-5D-5L is a validated generic patient-reported outcome measure (www.euroqol.org), including validation in patients with hip fractures and orthopaedic patients with cognitive impairment.; Timepoint(s): baseline, 2 weeks, 6 weeks, 12 weeks, 6-month time points as well as an optional 12 month follow up point for those recruited early within the study.

Secondary outcome measures

1. Physical function measured using Patient Reported Outcome Measures Information System (PROMIS) Lower Extremity Function at baseline, 2 weeks, 6 weeks, 12 weeks, 6 months
2. Physical function measured using Timed Up and Go Test (TUG) at 12 weeks
3. Mental health measured using PROMIS Scale v1.2 – Global Health Mental 2a at baseline, 2 weeks, 6 weeks, 12 weeks, 6 months
4. Pain measured by Numeric Rating Scale (NRS) at baseline, 2 weeks, 6 weeks, 12 weeks, 6 months
5. Delirium measured using Abbreviated Mental Test Score (AMTS) at baseline, 2 weeks, 12 weeks
6. Delirium measured using 4AT Rapid Assessment Test for Delirium at baseline, 2 weeks, 12 weeks
7. Complications measured using clinic review and/or patient self-report at 2 weeks, 12 weeks, 6 months
8. Mortality measured identified using central NHS records at 12 weeks, 6 months, 12 months (for those patients that agree to this additional follow-up)
9. Imaging - radiologic assessment of the pelvis performed at 12 weeks
10. Other outcomes: data on length of hospital stay, change of place of residence (e.g. own home to residential care home) and return to normal activities, measured using clinic review and /or patient self-report at 2 weeks, 6 weeks, 12 weeks, 6 months

Overall study start date

01/10/2018

Completion date

09/12/2021

Eligibility

Key inclusion criteria

Current inclusion criteria as of 26/03/2021:

1. Aged 60 years or older

2. LC-1 pelvic fracture arising from a low-energy fall from standing height or less
3. Patient unable to mobilise independently to a distance of around 3 m and back, due to pelvic pain (or perceived pelvic pain) 72 h after injury. Use of a walking aid and verbal guidance are permitted, however physical assistance is not.

Courtesy telephone call/postcard sub-study:

All participants recruited into the L1FE trial who consent to being contacted by telephone and by post will be eligible for the sub-study. There are no additional inclusion or exclusion criteria

Previous inclusion criteria:

1. Aged 60 years or older
2. An LC-1 pelvic fracture is diagnosed, arising from a low energy fall
3. After 72 hours post-injury the patient is unable to mobilise independently or with supervision (with or without a walking aid) to a distance of around 3 meters and back, due to pelvic pain or perceived pelvic pain

Courtesy telephone call/postcard sub-study:

All participants recruited into the L1FE trial who consent to being contacted by telephone and by post will be eligible for the sub-study. There are no additional inclusion or exclusion criteria

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Planned Sample Size: 600; UK Sample Size: 600

Total final enrolment

11

Key exclusion criteria

Current inclusion criteria as of 26/03/2021:

1. Surgery not able to be conducted within 10 days of injury
2. Surgery is contra-indicated because patient is not fit for anaesthetic (spinal or general) or soft tissue concerns
3. Patients who were non-ambulatory or required physical assistance to walk, prior to their injury (use of a walking aid is permitted)
4. Concomitant injury or poly-trauma that impedes mobilisation
5. Fracture configurations not amenable to internal fixation using INFIX, with or without ilio-sacral screws
6. Patients who test positive for COVID-19 within 72 h of admission (applicable only where testing is standard of care)

Courtesy telephone call/postcard sub-study:

There are no additional exclusion criteria for the courtesy telephone call sub-study

Previous exclusion criteria:

1. Unable to perform surgery within 10 days of injury
2. Surgery is contra-indicated because patient is not fit for anaesthetic (spinal or general) or soft tissue concerns
3. Patients who were non-ambulatory or required assistance walking, with or without a walking aid prior to their injury
4. Concomitant injury or poly-trauma that impedes mobilisation
5. Fracture configurations that the surgeon feels are not amenable to internal fixation using INFIX, with or without adjunctive ilio-sacral screws

Courtesy telephone call/postcard sub-study:

There are no additional exclusion criteria for the courtesy telephone call sub-study

Date of first enrolment

02/08/2019

Date of final enrolment

13/08/2021

Locations

Countries of recruitment

England

Scotland

United Kingdom

Wales

Study participating centre

Barts Health NHS Trust

The Royal London Hospital

Whitechapel

London

United Kingdom

E1 1BB

Study participating centre

North Bristol NHS Trust

Southmead Hospital

Southmead Road

Westbury-on-Trym

BRISTOL
United Kingdom
BS10 5NB

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

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

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough

United Kingdom
TS4 3BW

Study participating centre

NHS Lothian

Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust

Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre

Cardiff & Vale University LHB

Corporate Headquarters
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre

Plymouth Hospitals NHS Trust

Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Study participating centre

Hull and East Yorkshire Hospitals NHS Trust

Hull Royal Infirmary
Anlaby Road

Hull
United Kingdom
HU3 2JZ

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

Study participating centre
Leeds Teaching Hospitals NHS Trust
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
University Hospital Southampton NHS Foundation Trust
Mailpoint 18
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Aintree University Hospital NHS Foundation Trust
University Hospital Aintree
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Lower Lane
Liverpool
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L9 7AL

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House

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G12 0XH

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St George's University Hospitals NHS Foundation Trust
St George's Hospital
Blackshaw Road
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Study participating centre
Imperial College Healthcare NHS Trust
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Praed Street
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W2 1NY

Study participating centre
Nottingham University Hospitals NHS Trust
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Study participating centre
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Queen Elizabeth Medical Centre
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B15 2TH

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University Hospitals Of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Salford Royal NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Portsmouth Hospitals NHS Trust
De La Court House
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Barts Health NHS Trust

Sponsor details
The Royal London Hospital
Whitechapel
London
England
United Kingdom
E1 1BB
+44 (0)207 043 0734
research.governance@qmul.ac.uk

Sponsor type
Hospital/treatment centre

Website

<http://www.bartshealth.nhs.uk/>

ROR

<https://ror.org/00b31g692>

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/167/57

Results and Publications

Publication and dissemination plan

1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication
6. A letter will be sent to participants at the end of the study thanking them for their involvement and providing them with a short summary of the results
7. Additional files will be made available via the HTA website

Intention to publish date

31/03/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study (fully anonymised) will be available upon request after the publication of the study results from Prof. David Torgerson (David.Torgerson@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 | | 02/02/2023 | 06/02/2023 | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |
| Results article | | 01/03/2024 | 28/03/2024 | Yes | No |