ISRCTN16478561 https://doi.org/10.1186/ISRCTN16478561

Surgical versus conservative treatment of LC1 pelvic fractures in the elderly

Submission date
01/04/2019

Recruitment status
No longer recruiting

Registration date
08/04/2019

Overall study status
Completed

Last Edited
28/03/2024

Condition category
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
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 can 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
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
263397

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))

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

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

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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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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

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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
United Kingdom

England

Scotland

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
Fazakerley Hospital
Lower Lane
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United Kingdom
L9 7AL

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
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G12 0XH

Study participating centre
St George's University Hospitals NHS Foundation Trust
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
Imperial College Healthcare NHS Trust
St. Marys Hospital
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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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University Hospitals Of North Midlands NHS Trust
Newcastle Road
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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
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PO6 3LY

Sponsor information

Organisation
Barts Health NHS Trust

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

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?
Results article		01/03/2024	28/03/2024	Yes	No
Protocol article		02/02/2023	06/02/2023	Yes	No
HRA research summary			26/07/2023	No	No
	Participant information sheet				

Participant information sheet	Study website	11/11/2025	11/11/2025	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes