

# Surgical versus conservative treatment of LC1 pelvic fractures in the elderly

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<b>Registration date</b> 08/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/03/2024	<b>Condition category</b> 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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Liz Cook

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

263397

### **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](http://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

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S5 7AU

**Study participating centre**  
**Cardiff & Vale University LHB**  
Corporate Headquarters  
Heath Park  
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CF14 4XW

**Study participating centre**  
**Plymouth Hospitals NHS Trust**  
Derriford Hospital  
Derriford Road  
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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  
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**Study participating centre**  
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SO16 6YD

**Study participating centre**  
**Aintree University Hospital NHS Foundation Trust**  
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**Study participating centre**  
**NHS Greater Glasgow and Clyde**  
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**Study participating centre**  
**St George's University Hospitals NHS Foundation Trust**  
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**Study participating centre**  
**Imperial College Healthcare NHS Trust**  
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**Study participating centre**  
**Nottingham University Hospitals NHS Trust**  
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**Study participating centre**  
**University Hospitals Birmingham NHS Foundation Trust**  
Trust HQ, PO Box 9551  
Queen Elizabeth Medical Centre  
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Newcastle Road  
Stoke-on-Trent  
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ST4 6QG

**Study participating centre**  
**Salford Royal NHS Foundation Trust**  
Salford Royal  
Stott Lane  
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**Study participating centre**  
**Portsmouth Hospitals NHS Trust**  
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Queen Alexandra Hospital  
Southwick Hill Road

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## 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?
<a href="#">Results article</a>		01/03/2024	28/03/2024	Yes	No
<a href="#">Protocol article</a>		02/02/2023	06/02/2023	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes