ISRCTN10649958 https://doi.org/10.1186/ISRCTN10649958

Surgical vs non-surgical treatment of LC1 pelvic injuries

Submission date
13/08/2018

Recruitment status
No longer recruiting

Registration date
16/08/2018

Overall study status
Completed

Last Edited
30/01/2023

Condition category
Injury, Occupational Diseases, Poisoning

[_] 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) fractures of the pelvis make up around 60% of pelvic fractures. A proportion of these are termed as unstable, meaning that there is a greater risk of the bone fragments displacing over time. This may lead to difficulties with mobilising and prolonged periods of pain. Therefore it may be appropriate to stabilise these fractures through surgery. However, surgery also has some significant risks such as infection, nerve damage etc. Currently there is no evidence to support either surgical or non-surgical management of these fractures. This study aims to test the feasibility of carrying out a future large scale study to inform the most appropriate management of these injuries.

Who can participate?
Patients aged 16 and older with an LC1 fracture with complete sacral fracture

What does the study involve?
Participants are randomly allocated to either follow a surgical or a non-surgical treatment pathway. The exact details of these two pathways are left to the discretion of each patient's treating pelvic specialist. Participants are assessed at regular intervals to complete questionnaires relating to their symptoms and daily activities as well as a physical assessment of their walking. A small proportion of participants are asked to take part in an interview to examine their acceptance of the treatments, study design and assessments used. The number of patients recruited to the study and the completeness of the data are also assessed.

What are the possible benefits and risks of participating?
Participation in this study will help us to design a future study to inform the most appropriate treatment of patients with an unstable LC1 fracture in the future. It is hoped that the outcomes of this future study will provide clearer information on whether surgical treatment of these injuries is most appropriate.

Where is the study run from?
1. Southmead Hospital (UK)
2. John Radcliffe Hospital (UK)
3. University Hospital Coventry and Warwickshire (UK)

4. Royal London Hospital (UK)
5. St George's Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2018 to December 2020

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

Who is the main contact?
Mr Steven Barnfield
TULIPStudy@nbt.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mr Steven Barnfield

Contact details
North Bristol NHS Trust
Southmead Hospital
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB
+44 (0)117 4141690
TULIPStudy@nbt.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38613

Study information

Scientific Title
A randomised controlled trial of surgical versus non-surgical treatment of lateral compression injuries of the pelvis with complete sacral fractures (LC1) in the non-fragility fracture patient - a feasibility study

Acronym

TULIP

Study objectives
Lateral Compression (type 1) fractures of the pelvis make up around 60% of pelvic fractures. A proportion of these are termed as unstable meaning that there is a greater risk of the bone fragments displacing over time. This may lead to difficulties with mobilising and prolonged periods of pain. Therefore it may be appropriate to stabilise these fractures through surgery. However, surgery also has some significant risks such as infection, nerve damage etc. Currently there is no evidence to support either surgical or non-surgical management of these fractures. This study aims to test the feasibility of carrying out a future large scale study to inform the most appropriate management of these injuries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West – Central Bristol Research Ethics Committee, 02/07/2018, ref: 18/SW/0135

Study design
Randomised; Interventional; Design type: Treatment, Surgery

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
Pelvis fracture

Interventions
Patients with a pelvic fracture will be referred to one of the hospitals specialising in the treatment of these injuries. Those identified as having sustained an unstable LC1 fracture by their treating pelvic specialist, and meeting the criteria for inclusion in the study, will be approached to see if they would be willing to take part in the study. Patients will be asked to complete a written consent form to indicate their agreement to take part and will be asked to complete a series of short questionnaires relating to their daily activities and symptoms both prior to and since their injury. They will then be randomised by computer to follow either a non-surgical or surgical pathway.

Patients assigned to a non-surgical pathway will be allowed to mobilise according to the advice of their pelvic specialist and with the guidance of a physiotherapist using appropriate walking aids. This may involve a period where they are restricted from putting their full bodyweight through their pelvis. Patients will be reviewed by their pelvic specialist at 2 weeks following their injury, as per normal practice, to monitor for any movement in their fracture.

Patients assigned to surgical management of their fracture will have surgery to stabilise the broken bones, using metalwork to fix the pelvis, performed at the earliest opportunity by a specialist pelvic surgeon. Following the surgery they will be able to mobilise as guided by their surgeon and a physiotherapist. This may involve a period where they are restricted from putting their full bodyweight through their pelvis.

Follow-up of patients as part of the study will take place at 2 & 6 weeks, 3, 6, 9 and 12 months following randomisation. At all these time points they will be asked to complete the same series of questionnaires relating to their symptoms and daily activities completed when they initially agreed to take part in the study. Additionally patients will be asked to provide a few details on the rehabilitation they have received and any healthcare resources used (e.g. physiotherapy, GP visits etc) during their treatment.

These questionnaires will be posted to patients at all time points. If no response is received then they may be completed by telephone with a member of the research team at the site at which they were recruited. Alternatively, at 6 weeks, 3 and 12 months, they may be completed with patients during their normal clinical review. At 6 weeks, 3 and 12 months, when patients are being reviewed by their pelvic specialist as part of their usual care, they will also be asked to complete a simple test of their walking ability with an independent assessor who is unaware of the treatment they have received.

A small group of participants will be asked if they are willing to take part in a short interview to assess the acceptability of the study design, including the recruitment process, treatments and follow-up procedures. A group of staff involved in the recruitment and treatment of patients will also be invited to take part in a short interview to assess their views of the study treatments and study design. These interviews will help to inform the design of the future larger scale study.

Intervention Type
Procedure/Surgery

Primary outcome measure
The aim of this research study is to perform a feasibility study which will allow the researchers to plan a full definitive trial. A future trial will be deemed to be feasible if the overall recruitment rate is greater than 40% of potential participants per centre per month.

The objectives of this feasibility study are;
1. To produce a CONSORT (consolidated standards of reporting trials) diagram, reporting screening, recruitment, randomisation compliance and include allocation proportions by centre
2. To confirm the recruitment rates and percentage of eligible patients who agree to take part
3. To collect outcome data at 2 & 6 weeks, 3, 6, 9 & 12 months post injury to collate the completeness and spread of the data at different time points post injury
4. To identify the outcome measure to be used as the primary outcome on the basis of completeness of data, sensitivity to change over time, the presence of floor or ceiling effects and patient acceptability
5. To develop and refine methods for the collection of resource use data relating to both management pathways

6. To explore patient and staff views of randomisation, treatment and trial processes using qualitative interviews

Secondary outcome measures
The outcome measures being assessed in this feasibility study for use in a future definitive trial are;
1. Iowa pelvic score – a measure specific to outcomes after pelvic injury
2. Oxford Hip score – a functional score for patients after hip/pelvic injury
3. EQ-5D-5L – a generic quality of life score
4. ICECAP-A – a measure of capability for the general adult population for use in economic evaluation
5. Brief Pain Inventory – a measure of pain severity and its effect on the patient
All the above outcomes will be assessed at 2 and 6 weeks, 3, 6, 9 and 12 months to assess the most appropriate timepoints to be chosen for a future definitive trial.

In addition the patients functional ability will be measured using the Timed Up and Go assessment carried out by a blinded assessor at 6 week, 3 months and 12 months.

Overall study start date
01/04/2018

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. LC1 fracture with complete sacral fracture
2. 16 years and older

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
37

Key exclusion criteria

Current participant exclusion criteria as of 06/08/2019:
1. Unable to be randomised within 72 hours of having capacity to comprehend the study information following arrival at the major trauma centre
2. Fragility fractures resulting from low-energy trauma (fall from less than standing height)
3. Presenting medical condition which precludes surgical intervention
4. Unable to provide informed consent

Previous participant exclusion criteria:
1. No bony anterior pelvic ring injury
2. Unable to be randomised within 2 weeks of injury
3. Unable to mobilise for 6 metres prior to injury
4. Fragility fractures resulting from low-energy trauma (fall from less than standing height)
5. Unfit for anaesthesia
6. Unable to provide informed consent
7. Unable to adhere to Protocol

Date of first enrolment
09/07/2018

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
Southmead Road
Bristol
United Kingdom
BS10 5NB

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

Study participating centre

University Hospital Coventry and Warwickshire
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1BB

Study participating centre
St George's Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 4149330
Researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0816-20013

Results and Publications

Publication and dissemination plan
The aim is to present the results from this feasibility study locally at each recruitment site, nationally at the Orthopaedic Trauma Society Annual meeting and also at the British Orthopaedic Association annual meeting to the general orthopaedic community. The results will be submitted for publication as an original article in a peer reviewed open access journal, possibly the BJJ (Bone & Joint Journal) or the JOT (Journal of Orthopaedics and Trauma). It is anticipated that potential publications will discuss the methodology of the study, including the outcome measures used and their ease of use by patients. As well as this it is hoped that the study will show the timepoint in patients recovery from these injuries where changes in their outcome are most significant and therefore the timepoint at which any primary outcome should be assessed. The study should also be able to provide some insight into patients views on the two treatment options and their willingness to be randomised to these treatments.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The anonymised, full trial dataset will be stored on a REDCap database located on the University of Bristol servers. Access to the final trial dataset will only be available to members of the Trial Management Group (TMG) and Statistician. Individual sites will be given access to the dataset for their own recruited patients only. This will be made available following the final publication and on receipt of a written request to the TMG. Requests for other study documents will be considered by the TMG and should be made in writing to the contact details above.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/02/2020	13/02/2020	Yes	No
Basic results			30/01/2023	No	No
HRA research summary			28/06/2023	No	No