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Treatment of stable thoracolumbar fractures: feasibility

Submission date	Recruitment status	[X] Prospectively registered
19/02/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/02/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/11/2021	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims

A thoracolumbar fracture is a break of the spine in the mid to low back and is the most common spine fracture. It is usually caused by trauma such as a traffic accident, a fall from height or certain sports. Many surgeons agree that when the fracture could be easily moved out of place and involves nerve damage, surgery is needed. When the injury is a fracture that will stay in place, with no nerve damage, it can be treated without surgery. This usually means using a brace to hold the spine still and slowly increasing activity. Some injuries are in the middle of these two types of fracture. Some surgeons might be more likely to fix these fractures with surgery. However, other surgeons are more likely to use a brace to stabilise the spine. There are risks and benefits with both treatments. Although both treatments are used widely throughout the NHS, it is not clear which works best. The best way to find out is to complete a randomised controlled trial but this may be difficult to do because surgeons and patients might have strong ideas about which treatment they prefer. Due to these challenges a study to find out if a larger trial would be possible is needed. This study will have the following aims: to test if we can recruit enough people to a full trial to compare surgery with non-operative treatment for mid-low spinal fractures and to test if we can collect the data needed to answer the research question.

Who can participate?

Patients aged 16 years or older with spinal fractures.

What does the study involve?

Participants are randomly allocated to one of two groups. One group will receive surgery and the other will be managed without surgery. Participants are advised about what will happen if it becomes necessary to change treatment at a later date. Participants are asked to complete questionnaires about their activity and quality of life. Routine X-rays and CT scans are used to assess spinal alignment and fracture healing at 3 and 6 months. All trial visits and scans are in line with the appointments that would usually be needed for clinical care. Some participants and surgeons involved in the study are invited to take part in an interview to help design the main trial. A national survey of surgeons is undertaken to investigate if they would be willing to recruit patients to a future trial. At the end of the study recommendations are made about whether a full trial is feasible and how the design of the study could be improved.

What are the possible benefits and risks of participating?
Because it is not known what treatment is best, there is no specific benefit to the patients taking part other than the potential to inform future clinical practice and to help future patients decide which treatment is best for them. There are no foreseen clinical concerns. All of the treatments offered as part of this study are used in routine NHS practice and therefore it is not anticipated that there are any ethical issues relating to our choice of treatments. Imaging procedures will be those routinely used for the investigation and follow-up of patients with fractures of the thoracolumbar spine following surgical or conservative management therefore there trial participants will not be exposed to ionising radiation above that of standard care.

Where is the study run from?
1. The Royal London Hospital (UK)
2. St. James's University Hospital (UK)
3. University Hospital of Wales (UK)

When is the study starting and how long is it expected to run for?
September 2017 to September 2019

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

Who is the main contact?
Mrs Liz Cook (Scientific)

Contact information

Type(s)
Scientific

Contact name
Mrs Liz Cook

Contact details
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Additional identifiers

Protocol serial number
37065

Study information

Scientific Title
Surgical fixation versus non-operative management for patients with stable thoracolumbar fractures: a feasibility study

Acronym
PRESTO

Study objectives
The aim of this study is to establish whether it is feasible to deliver a trial comparing surgical fixation to initial non-operative management for patients with a stable thoracolumbar fracture without spinal cord injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East – Newcastle & North Tyneside 1 Research Ethics Committee, 18/NE/0008

Primary study design
Interventional

Study design
Randomised; Both; Design type: Treatment, Surgery, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Thoracolumbar fractures

Interventions
The trial objectives will be addressed through three elements:
1. A randomised pilot study
2. A national survey of surgeons
3. A qualitative study

Randomised Pilot Study: This is a pragmatic, parallel group, randomised controlled trial comparing arm 1 (intervention) versus arm 2 (control):
Arm 1: Surgical fixation (open or pedicle screw fixation)
Arm 2: Non-operative management (mobilisation in a brace, or mobilisation without a brace)
Participants are allocated to surgical fixation or initial non-operative management by independent concealed random allocation using block randomisation stratified by centre and type of injury (high-energy trauma or low-energy osteoporotic).
There is a 12 month recruitment period, across three centres, which is long enough to reliably measure the feasibility outcomes.
The primary effectiveness and cost-effectiveness data collection are completed at 3 months (6 months for those patients that reach this time point by the end of the trial).

Some participants and surgeons involved in the study are invited to take part in an interview to help design the main trial.

A national survey of surgeons will be undertaken to investigate if they would be willing to recruit patients to a future trial.

Intervention Type
Other

Primary outcome(s)
Recruitment rate, defined as the proportion of eligible participants who are randomised during the recruitment period.

Key secondary outcome(s)
Feasibility is measured using:
1. Recruitment rates as defined as:
1.1. Number of eligible patients
1.2. Proportion of eligible patients approached for consent
1.3. Proportion of eligible patients not approached for consent and reasons why
1.4. Proportion of patients approached who provide consent
1.5. Proportion of patients approached who do not provide consent and reasons why
2. Randomisation:
2.1. Proportion of patients providing consent who are randomised
2.2. Proportion of patients randomised who do not receive the randomly allocated treatment and reasons why
3. Cross-over is measured as the proportion of patients randomised to the non-operative treatment who receive surgical management, at what time point and reasons why
4. Drop-out rate as defined as the proportion of patients dropping out between randomisation and follow-up at 2 weeks, 3 months and 6 months and reasons why
5. Ability to collect clinical outcome measures:
5.1. Feasibility of gathering patient reported outcome measures and other outcome measures at baseline and follow-up at 2 weeks, 3 months and 6 months (proportion of complete data for each outcome measure; proportion successfully gathered through the British Spine Registry)
5.2. Oswestry Disability Index (ODI): Collected at baseline, 3 and 6 months
5.3. Visual Analogue Scale (VAS) for pain: Collected at baseline, 3 and 6 months
5.4. Short Form-12 (SF12): Collected at baseline, 3 and 6 months
5.5. EuroQol 5 Dimensions (5L) Score (EQ5D-5L): Collected at baseline, 3 and 6 months
5.6. Kyphotic angle is measured using COBB technique at baseline, 2 weeks, 3 months and 6 months. This will be measured from imaging routinely performed at these timepoints
5.7. Feasibility of gathering data on complications and adverse events (proportion of complete data)
6. Feasibility of appropriate and accurate economic data collection
7.To inform the design of the future trial we will also gather data on:
7.1. Participant treatment preferences at baseline
7.2. Clinical care during the trial:
7.2.1. Methods used to establish spinal stability
7.2.2. Details of surgical fixation used
7.2.3. Details of non-operative management

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. Age 16 years or older
2. Diagnosis of a high- or low-energy impact thoracolumbar vertebral fracture, between T10 and L2, and confirmed by radiograph, computed tomography (CT) scan or magnetic resonance imaging (MRI) with any ONE of the following criteria:
2.1. A kyphotic angle greater than 20 degrees on standing radiographs, or if lying CT or radiograph then 15 degrees of kyphosis or
2.2. Reduction of vertebral body height by 25 percent or
2.3. Fracture line propagating through the posterior wall of vertebra or
2.4. Two contiguous vertebrae involved or
2.5. Injury to the posterior longitudinal ligament (PLL) or annulus in addition to the body fracture

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
12

Key exclusion criteria
1. Unstable fractures which obviously need surgical stabilisation – decision made by the treating surgeon
2. Spinal cord injury
3. Pathological (other than osteoporotic) fracture e.g. tumour / infection
4. Patient not considered suitable for surgery

Date of first enrolment
01/03/2018

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
Whitechapel
London
United Kingdom
E1 1BB

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

Study participating centre
University Hospital of Wales
Cardiff and Vale University Health Board
Heath Park Way
Cardiff
United Kingdom
CF14 4XW

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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:
Professor 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	protocol	01/11/2021	16/11/2021	Yes	No
Protocol article		13/03/2020	20/03/2020	Yes	No
HRA research summary			28/06/2023	No	No