ISRCTN60891364 https://doi.org/10.1186/ISRCTN60891364

Evaluating a rehabilitation protocol following lumbar fusion surgery

Submission date
10/07/2014

Recruitment status
No longer recruiting

Registration date
10/07/2014

Overall study status
Completed

Last Edited
05/03/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Lumbar fusion surgery is a large and complex operation that involves placing screws and rods into the lower back. This is done to help people who are affected from lower back pain and sciatica (nerve pain that runs down one or both legs). In many cases the surgery does not relieve all the pain and people can still have pain and disability for years after the operation. Research has shown that offering people rehabilitation after some types of spinal surgery can be helpful in addressing these problems. This study is designed to see if it is possible to provide people with quite complex rehabilitation after surgery. It will also see whether this approach helps their recovery.

Who can participate?
Patients aged 18 to 75 years who are waiting to receive lumbar fusion surgery in the participating hospital can take part.

What does the study involve?
The study will involve asking people who have decided to have this operation if they would like to consider joining our study. If they agree to join the study we will randomly decide which group they should go into. This decision is made randomly, which means that no member of the research team, the surgeon or the person themselves can choose which treatment they receive after their operation. This is similar to tossing a coin. The study will have two groups of people in it. One group, called usual care, will have all the usual surgical aftercare that people receive after this operation. This includes advice and physiotherapy. The other group, called the rehabilitation group, will be asked to come along to our rehabilitation group after surgery. This takes place once per week for 10 weeks and each session lasts about 90 minutes. Each session involves advice, exercises and sharing experiences with other people who have had a lumbar fusion. Both groups will not begin until the surgeon has reviewed the people at 3 months after the operation to ensure that they are fit and well enough to participate. All the people will have their operation as planned and being part of the study will not affect this at all. Everyone will have all the normal care that people get after this operation. This involves treatment in the hospital to ensure they are well enough to go home. Once they are fit to go home they will be given advice on how to slowly progress their activity levels. Everyone will also have check-up with their surgeon 6 and 12 weeks after the operation. If the surgeon is happy that everything is

satisfactory at 12 weeks after the operation the participants will be able to begin rehabilitation (either as usual care or as part of the rehabilitation group). At 6 months after the operation they will again be seen by their surgeon to have another check-up. The person in charge of the study will ask everyone in the study to fill out some questionnaires and perform a short physical test. This is done to see how they are progressing.

What are the possible benefits and risks of participating?
It is possible that attending the rehabilitation group will be helpful to people. We have run a smaller study previously and people generally improved with rehabilitation. However, it is by no means sure that by attending the rehabilitation group people will gain any benefit. It is very unlikely that there will be any problems related to attending the rehabilitation group. Exercise after fusion surgery is generally accepted to be safe as long as it is not begun too early and the surgeon is happy with the progress of the operation.

Where is the study run from?
The National Hospital for Neurology and Neurosurgery, which is part of UCLH NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
June 2014 to December 2016

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

Who is the main contact?
Mr James Greenwood
james.greenwood@uclh.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mr James Greenwood

Contact details
Centre for Medical Imaging
235 Euston Road
London
United Kingdom
NW1 2BU
-
james.greenwood@uclh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16761

Study information

Scientific Title
Evaluating a rehabilitation protocol following lumbar fusion surgery (REFS): a feasibility study

Study objectives
Approximately 40% of patients following lumbar fusion surgery would rate themselves as clinically unchanged or worse at 2 years post surgery. The outcomes of some forms of spinal surgery can be improved with rehabilitation. We aim to see if it is possible to provide small groups of complex rehabilitation to patients 3 months after they have undergone a technically successful lumbar fusion. This will evaluate recruitment and compliance as well as secondary measures of clinical outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/LO/0748; First MREC approval date 13/06/2014

Study design
Randomised; Interventional and Observational; Design type: Process of Care, Qualitative

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
Topic: Musculoskeletal disorders; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
Patients (aged 18-75, listed for elective lumbar fusion for degenerative disease) will be selected from the neurosurgical waiting list. Those that express an interest in the study will be given the

patient information sheet. They will then discuss the study with the CI at a pre-operative assessment. Those that agree to enroll will be asked to provide consent and baseline data preoperatively. Participants will then be randomised to either the rehabilitation group or usual care. Randomisation will be via block randomisation using codes generated at a remote site. These will be concealed by the use of sealed, numbered, opaque envelopes. We aim to recruit 50 participants over 30 months.

All participants will receive identical post-operative management during their hospital stay and for the first 12 weeks. This involves a relative reduction in activity; they are not allowed to lift anything heavier than a kettle and are advised to steadily increase their outdoor mobility within the bounds of pain up to a maximum of 2 miles. All participants will have a review with the surgical team at 6 and 12 weeks post-operatively in accordance with normal clinical practice. Following a satisfactory 12-week post-operative surgical review (absence of technical failure of the construct, e.g. infection, loosening) participants will begin their allocated post-operative care (usual care or rehabilitation).

1. Usual care consists of a single advice session to progressively increase physical activity within the bounds of pain. Further treatment such as referral to a physiotherapist will be at the discretion of the surgical team or general practitioner. Participation in the study will not preclude any post-operative treatment that is deemed necessary.

2. Those participants randomised to the rehabilitation group will be invited to attend. The group runs once per week for 10 consecutive weeks, and each session lasts a maximum of 90 minutes. Each session consists of a brief educational session utilising principles of CBT, individualised, supervised, progressive exercises and concludes with a peer support session.

Data collection occurs at baseline (pre-operatively) 3, 6 and 12 months post-operatively. Surgical follow-up occurs at 6 weeks, 3, 6, 12 and 24 months post-operatively.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Feasibility; Timepoint(s): Assessment of willingness to participate, compliance etc

Secondary outcome measures
Oswestry disability index (ODI)

Overall study start date
01/06/2014

Completion date
01/12/2016

Eligibility

Key inclusion criteria

50 subjects will be recruited between the ages of 18-75 years of age, with or without radicular leg pain who have been placed on the waiting list for elective lumbar fusion surgery at the NHS host

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50; Description: The group of total participants n=50 will be randomly split into two equal groups

Key exclusion criteria
1. Spinal cord involvement
2. Post-operative complications
3. Revision fusion surgery (previous history of decompressive surgery will be eligible)
4. Lower limb joint pain which interferes with assessment or ability to exercise
5. Can walk less than 20 m
6. Severe, poorly controlled psychological or physical co-morbidity
7. Inadequate verbal and written English
8. Unable or unwilling to undertake exercise, attend post-operative programme or to give signed consent

Date of first enrolment
01/06/2014

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Centre for Medical Imaging
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

Sponsor details
The Hatter Institute for Cardiovascular Studies
25 Grafton Way
London
England
United Kingdom
WC1E 6DB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Government

Funder Name
NIHR Clinical Doctoral Research Fellowship (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mr James Greenwood (james.greenwood@uclh.nhs.uk). Anonymised data will remain available for 5 years from the end of the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/06/2015		Yes	No
Results article	results	01/04/2019	05/03/2019	Yes	No
HRA research summary			28/06/2023	No	No