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The spinal fusion indications and outcomes randomised trial

Submission date 03/05/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/05/2019	**Overall study status** Completed	
Last Edited 10/06/2024	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Many patients suffer from lower back pain due to a condition called spinal stenosis. There are two operations in routine use to treat this. The researchers want to run a large study to find out which is best, but such a trial will not be easy to conduct. Before they do a large study like this they need to consider how a study like this would work in practice. They need to know if patients would be willing to take part, how they feel about the two different operations and how they should measure “success” after the operation. This is called a feasibility study and will show whether a larger study is possible and how it should be run.

Who can participate?
Patients aged over 40 with spinal stenosis and additional criteria, assessed by their consultant surgeon.

What does the study involve?
Participants complete a consent form and some questionnaires, before being randomly allocated to be treated by either operation A or B. Both these operations happen under general anaesthetic as per routine care.
A – Decompression: This operation removes small sections of bone on the vertebrae on the spine that are putting pressure on the nerves.
B – Decompression with Instrumented Fusion: as with decompression, the surgeon removes small sections of bone to relieve pressure on the nerves. They also fix the vertebrae in the spine in place with metal rods and screws.
After the operation, there is no change to the care participants would normally receive. An X-ray is taken at a follow-up appointment 3 months after surgery. The measurements from this are used for the study. Patients complete questionnaires about their health and recovery 3 and 6 months after starting the study. Patients are also asked if they would like to be part of a focus group to discuss their experiences of the study.

What are the possible benefits and risks of participating?
The researchers cannot guarantee a benefit to patients who take part in this study. The results

from the study are likely to benefit future patients with similar conditions. Taking part in the study will not change the standard of care patients receive. Both operations are already done in the NHS; there are no additional risks associated with taking part in the study.

Where is the study run from?
The University of Oxford is the study sponsor, meaning they are responsible for the study. The Surgical Intervention Trials Unit in Oxford and the Oxford Clinical Trials and Research Unit are supporting the study management.

When is the study starting and how long is it expected to run for?
January 2019 to September 2020

Who is funding the study?
National Institute for Health Research (NIHR), Research for Patient Benefit (RfPB) programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
40853

Study information

Scientific Title
The spinal fusion indications and outcomes randomised trial – a feasibility study

Acronym
SPINOUT

Study objectives
As people age, there is increasing wear on the bones in their spine. The spine responds to this by producing extra bone and changing its shape, sometimes with one vertebra slipping on another. These changes can narrow the normal spaces where nerves pass through the spinal cord, creating an unstable spine. When the nerves get pressed, back and leg pain occurs with substantial interference on daily life and on mental and physical well-being. When severe, surgery may be necessary to relieve that pressure. This is now the most common spinal disorder requiring surgery. 18,000 procedures are performed each year in the NHS.
Surgical treatment can involve decompression surgery - removing the bone that presses on the nerves. It could also involve the insertion of screws and rods (called an instrumented fusion) to support the spine. There is no evidence and no agreement between surgeons as to which is better. The decompression surgery might need a revision sooner, but instrumented fusion might be too invasive for a first line surgical treatment.
Ultimately a research study called a randomised trial is needed to inform this decision but such a trial will not be easy to conduct. Before the researchers do a large study like this they need to consider how a study like this would work in practice. They need to know if patients and surgeons would be willing to take part, how they feel about the two different operations and how they should measure “success” after the operation. This is called a feasibility study and will show whether a larger study is possible and how it should be run to give an answer to this clinical question.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/04/2019, East Midlands – Leicester South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, Tel: +44 (0)207 104 8109; Email: nrescommittee.eastmidlands-leicestersouth@nhs.net), ref: 19/EM/0068

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

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Spinal fusion

Interventions

SPINOUT-F is a feasibility study, consisting of a randomised pilot trial and patient focus groups.

Randomised pilot
Patients will be recruited via outpatient clinics. They will have the opportunity at this appointment to ask any more questions they have about the study. Screening forms will be completed at each site. These will detail any reasons for exclusion and non-participation. Patients will be randomised to receive one of two possible interventions. Randomisation will function via the OCTRU RRAMP online system. Group 1 will have decompression, Group 2 will have decompression and instrumented fusion. Both procedures will take place under general anaesthetic.

A panel of surgeons made up of the site PIs will agree on the specifics of the surgical approach for each patient. This will be coordinated centrally from the study office. A minimum of two surgeons will be required to agree on the approach to ensure consistency in the treatment delivered. Images necessary for the review will be anonymised and circulated to the PIs by the operating surgeon, along with a panel review form to complete. If there is disagreement, a panel meeting/teleconference will be organised to reach a consensus.

Trial follow up will also be in the form of remote patient questionnaires. Topics include the ability to perform activities of daily life, pain and health economics. These will be sent either through post or email, according to patient preference. All patients will be sent a questionnaire at 3 month post-randomisation. For those who reach 6 months post-randomisation within the study recruitment window, they will be sent the same questionnaire at this time point as well. Patients will also have a post-operative X-ray at their 3-month post-operative clinic. This is part of routine clinical care, and data reported on this will be collected as part of the trial follow-up data.

Qualitative interviews and focus groups
Pilot study participants who agree to be contacted will be invited to take part in focus groups. Focus groups allow participants to speak freely about their concerns and offer their views about the study. They help identify issues that resonate with patients, carers and the public at large in matters of healthcare. Patients not participating in the study may also be approached to participate in the focus groups. Other patients may also be invited as per routine patient involvement methods at participating sites.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The practicability of a multicentre RCT of instrumented spinal fusion in addition to decompression surgery compared to decompression surgery alone. This will be measured by the completion of both recruitment and follow up in a randomised pilot study at the end of the study period.

Key secondary outcome(s))
1. The availability of sufficient eligible patients and ability to recruit across sites at an adequate rate. This will be measured by the identification of eligible patients recorded on screening forms at the end of the study period
2. Adherence to allocated surgery and intended surgical approach. This will be measured by the completion of allocated surgical procedure at the end of the study period
3. Whether the surgical approaches can be standardised and delivered appropriately across

multiple sites/surgeons. This will be measured by the compliance with protocol requirements at the end of the study period
4. Ability to collect key follow-up data. This will be measured by the completion of follow-up at 3 months post randomisation.
5. Quality of life after surgery. This will be measured by the Visual Analogue Scale, Oswestry Disability Index, Measure Yourself Medical Outcome Profile and EQ-5D-5L at 3 months post randomisation
6. Post-operative spinal curvature. This will be measured by post-operative X-rays at 3 months post randomisation
7. The feasibility of an definitive economic evaluation of instrumented fusion and decompression. This will be measured by health resource use and EQ-5D-5L at 3 months post randomisation
8. The outcomes that are relevant and important to patients to inform the main trial. This will be measured by the themes identified in patient focus groups at the end of the study period

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Over 40 years of age
2. Radicular leg pain or claudication symptoms greater than or equal to back pain for whom surgery is considered an option
3. Failed conservative treatment (eg physiotherapy, injections, pain medication)
4. Either:
4.1. Confirmed nerve compression in the lateral recess or exit foramen or
4.2. Central spinal stenosis with cross-sectional area of the dural sac of <70mm2 in the MRI on 1 or 2 levels corresponding to L3/4, L4/5 or L5/S1
5. Confirmed diagnosis of either or both:
5.1. Loss of lumbar curvature (spino-pelvic malalignment) measured as pelvic incidence-lumbarlordosis mismatch of >10° measures on lateral radiograph with inclusion of femoral heads and/or
5.2. Degenerative spondylolisthesis with an increase of the slip on the standing radiograph compared to the supine MRI to more than >25% or >5mm translation on a standing lateral radiograph indicating a higher degree slip

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Sex
All

Total final enrolment
6

Key exclusion criteria
1. Isthmic spondylolisthesis
2. Previous spinal surgery in the thoraco-lumbar spine
3. Degenerative scoliosis of the lumbar spine of > 10°
4. Smoking
5. Body mass index > = 35 kg/m2
6. Clinical history of osteoporotic fracture or chronic oral steroid use
7. Evidence of neurological disorders (eg multiple sclerosis, Parkinson's) or systemic illnesses (eg inflammatory arthritis) that effect physical function
8. Unable to give informed consent
9. Patients who are involved in any other ongoing research

Date of first enrolment
17/06/2019

Date of final enrolment
30/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
Stanmore
United Kingdom
HA7 4LP

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0317-20035

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/08/2023	10/06/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes