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Laminectomy or X-Stop – Which operation is more cost-effective for Lumbar Spinal Stenosis?

Submission date
06/05/2008

Recruitment status
No longer recruiting

Registration date
04/06/2008

Overall study status
Completed

Last Edited
03/02/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Lumbar spinal stenosis is a common condition of the spine affecting mainly the older population. It causes back pain and pain down the legs and impairs mobility, therefore it has a negative impact on the individual's quality of life. An operation can help to alleviate some of these symptoms. Laminectomy is the standard operation that is offered however this is quite invasive and not always successful. It also has a considerable risk of complications. A new device called X-stop is an implant that can be inserted in between the bones of the spine to achieve the same effect or similar to a laminectomy. The latter is a relatively minor operation where the risk of complications is less, however, the device itself is very expensive and is not proven to be better than a laminectomy. The aim of the study is to find out which operation results in a better quality of life and which one is more cost-effective.

Who can participate?
Adult patients with lumbar spinal stenosis

What does the study involve?
Patients with Lumbar Spinal Stenosis who are candidates for surgery and who agree to participate in the trial are randomly allocated to either a Laminectomy or X-Stop operation. They are asked to complete questionnaires before and after surgery and are followed up for two years.

What are the possible benefits and risks of participating?
Patients follow normal NHS pathways and as such there are no benefits to participate in the trial. The follow up for the trial is two years however, and normally patients would be discharged before that. Therefore, participants in the trial are likely to get longer follow up than usual. Participation is voluntary and patients may withdraw from the study at any point. Patients who agree to participate are unable to choose which operation they will have. Also they are asked to complete several questionnaires prior to surgery and again at 6, 12 and 24 months post operatively which wouldn't be required outside the trial.

Where is the study run from?
1. The National Hospital for Neurology and Neurosurgery (UK)

2. St George’s Hospital (UK)
3. Hurstwood Park Neuroscience centre (UK)

When is the study starting and how long is it expected to run for?
April 2008 yo August 2017

Who is funding the study?
Kyphon Europe (Belgium)

Who is the main contact?
Mr David Choi
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
07/X01

Study information

Scientific Title
Cost effectiveness and quality of life after treatment of lumbar spinal stenosis with the X-STOP® Interspinous Process Distraction (IPD) device or laminectomy: a prospective randomised trial

Acronym

CELAX - Cost Effectiveness of lumbar LAminectomy versus X-STOP®

Study objectives
Null hypothesis: There is no difference in cost effectiveness, clinical efficacy, quality of life and safety of the X-STOP® device compared to that of conventional lumbar decompressive surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Charing Cross Research Ethics Committee, 01/04/2008, ref: 08/H0711/12

Study design
Multicentre prospective randomised controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Neurogenic intermittent claudication secondary to lumbar spinal stenosis

Interventions
Participants will be randomly allocated to the one of two treatment groups. A five block randomisation process will be used and patients are randomised the day before surgery.

Lumbar laminectomy: Participants receive a standard surgical decompression where the laminae at the affected level are removed. The operating surgeon’s discretion is used to determine the extent of the decompression including undercutting of the facet joints and whether a drain is required.

X-STOP® interspinous distractor: Patients have the device inserted at the affected level.

Participants in both groups complete follow up questionnaires post-operatively, and after six months and one and two years.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Cost of implanting X-stop interspinous distractor compared to conventional surgical decompression

Secondary outcome measures
The following will be assessed preoperatively, on discharge, at 6 weeks, 6, 12 and 24 months:
1. Quality of life, assessed by the EQ-5D, 36-item Short Form health survey (SF-36) and Quebec Back Pain Disability Questionnaire
2. Clinical efficacy, assessed by the Zucher Claudication Questionnaire (ZCQ), Oswestry Disability Index (ODI) and visual analogue scale (VAS)
3. Safety (any complication either perioperatively or postoperatively)

Overall study start date
01/04/2008

Completion date
01/08/2017

Eligibility

Key inclusion criteria
1. Age: 18-80
2. Sex: males and non-pregnant females
3. Chronic leg pain with or without back pain of greater than 6 months duration, partially or completely relieved by adopting flexed posture and who are suitable candidates for posterior lumbar surgery
4. Those who have completed at least 6 months of conservative treatment without obtaining adequate symptomatic relief
5. Degenerative changes at one or two adjacent levels between L1-S1 confirmed by X-ray, computerised tomography (CT) or magnetic resonance imaging (MRI) scan

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants

110 (55 in each treatment group)

Total final enrolment
47

Key exclusion criteria
1. Fixed motor deficit
2. Active infection or metastatic disease
3. Degenerative spondylolisthesis >= Meyerding Grade 2
4. Known allergy to implant materials
5. Severe osteoporosis or rheumatoid arthritis
6. Cauda equina syndrome

Date of first enrolment
11/12/2008

Date of final enrolment
01/02/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The National Hospital for Neurology and Neurosurgery
Queen Square
London
United Kingdom
WC1N 3BG

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

Study participating centre
Hurstwood Park Neuroscience centre
Princess Royal Hospital

Hayward’s Heath
United Kingdom
RH16 4EX

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.uclh.nhs.uk

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Industry

Funder Name
Kyphon Europe (Belgium)

Results and Publications

Publication and dissemination plan

Planned publication in a per reviewed journal.

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Anouk Bord (anouk.borg@nhs.net)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/02/2021	03/02/2021	Yes	No