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Comparison of two different surgical approaches to decompress lumbar spinal nerves in patients with narrow lumbar spinal canal and instability

Submission date
03/11/2016

Registration date
03/12/2016

Last Edited
23/02/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Spinal fusion surgery (spondylodesis) is a type of surgical procedure which joins two or more vertebrae (small bones that make up the spine) together. It is more often used to treat a condition called spondylolisthesis, where one of the vertebrae slips out of position onto the vertebra below it. There are different approaches to this type of surgery however it is not known which is most effective. The most commonly used method involves fusing the spine with something called a pedicle screw, which anchors the vertebrae together. Although it is an established technique, it is still a very invasive procedure with high complication rates. Therefore, minimally invasive approaches were developed, the medialized bilateral pedicle screw fixation (mPACT) being one of them. The aim of this study is to compare the safety and efficiency of these two procedures.

Who can participate?
Adults with spondylolisthesis who require spinal fixation surgery.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo surgery using the pedicle screw technique and those in the second group undergo surgery using the mPACT technique. Participants in both groups complete a number of assessments and questionnaires at the start of the study, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery, in order to find out how successful the surgery was.

What are the possible benefits and risks of participating?
This study does not intervene in the therapeutic decision process of the patients and in the surgical procedure. All participants will receive the same standardized postoperative treatment regime already established in the our center. No additional treatments are required for this study. Postoperative evaluation for study purposes will not differ between the study groups. Patients might benefit from a more frequent and standardized postoperative monitoring and

documentation. Since these two techniques are well-established and this study does not intervene in the therapeutic decision process and in the surgical procedure, there is no additional risk for the patient when participating in this study.

Where is the study run from?
The study is run from International Centre for Diarrhoeal Disease Research, Bangladesh and takes place in villages in Khishoreganj district (Bangladesh)

When is the study starting and how long is it expected to run for?
July 2016 to August 2018

Who is funding the study?
Medical University of Innsbruck (Austria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
v04.10.2016

Study information

Scientific Title
Clinical and radiological effect of cortical bone trajectory for lumbar pedicle screw fixation in patients with degenerative lumbar spondylolisthesis

Acronym
mPACT

Study objectives
The aim of this study is to compare the conventional transpedicular titanium-based pedicle screw instrumentation with the „medialized posterior approach with cortical trajectory“ technique (mPACT) with decompression in patients suffering from symptomatic degenerative disc disease or degenerative spondylolisthesis requiring one-, two- or three-level lumbar or lumbo-sacral spinal fusion.

Null hypothesis:
There is no difference in the oswestry disability index (ODI) after the operation at five years follow-up.

Experimental hypothesis:
There is a difference in the oswestry disability index (ODI) after the operation at five years follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical University of Innsbruck (Ethikkommission der Medizinischen Universität Innsbruck), 13/10/2016, ref: AN2016-0168 365/4.1

Primary study design
Interventional

Study design
Prospective monocentric randomized controlled descriptive trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Spondylodesis

Interventions
Participants are randomised to one of two groups in a 1:1 ratio using a randomisation list.

Group 1: Participants receive a lumbar decompression and fusion with a medialized cortical bone trajectory. This involves a rigid interbody fusion with a cortical bone trajectory. It is performed by identifiying the super most lateral edge of the pars and moving 2 to 5mm medial to identify the screw entry point. Typically, the screw is placed with an approximately 15° medial to lateral trajectory.

Group 2: Participants receive a lumbar decompression and fusion with a conventional bone trajectoy. This involves a rigid interbody fusion with a titanium-based pedicle screw instrumentation. Group 2 as the control group needs to represent the gold standard of care.

Participants in both groups are followed up by the subinvestigators of the site at 3, 6, 12, 24, 36, 48 and 60 months after surgery. Follow up involves clinical history, neurological status, quantitative sensory testing, blood sample collection and imaging of the lumbar spine (X-ray, MRI, CT).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Overall success is measured using the oswestry disability index (ODI) at baseline, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery.

Key secondary outcome(s)
1. Depression is measured using the Beck depression inventory (BDI) at baseline, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery
2. Pain, back specific function, work disability and patient´s satisfaction are measured using The Core Outcome Measures Index (COMI) at baseline, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery
3. Generic health status is assessed with the EuroQoL-5Dimension (EQ-5D) at baseline, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery
4. Neuropathic pain components are measured the painDETECT questionnaire (PD-Q) at baseline, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery
5. Physical ability of walking is measured using the timed up and go (TUG) test at baseline, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery
6. Pain relief is measured using a 100 mm visual analoge scale (VAS) at baseline, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery
7. Lumbar back pain is measured using Quantitaitve sensory testing at baseline, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery
8. IL-6, TNF alpha, CRP and Leucocyte levels are measured using blood testing at baseline, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery
9. Degeneration of treatment levels as well of the adjacent discs is measured using MRI of the lumbar spine at baseline, 24 and 60 months after surgery
10. Degeneration of the treatment level as well of the adjacent lumbar discs is measured ad baseline and overall fusion rate is detected 12 months after surgery using CT of the lumbar spine.
11. Sagittal alignment or possible adjacent disc disease will be assessed using x-ray at baseline, 3 days and 3, 6, 12, 24, 36, 48 and 60 months after surgery.
12. Adverse events will be documented by the clinical team continuously until 60 months post-surgery
13. Intraoperative parameters (blood loss, time of surgery) will be documented throughout surgery

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Clinical signs of lumbar degenerative stenotic disease from L1 to S1
2. MRI and CT confirmed: central canal stenosis OR lateral recesses stenosis OR foraminal stenosis leading to:
2.1. Radiculopathy, defined as pain and/or motor weakness or paralysis and/or paraestethica in a at least one specific nerve root distribution from L1 to S1 or
2.2. Neurogenic intermittent claudication, defined as pain and/or weakness and/or abnormal sensation in the legs during walking or prolonged standing

3. Indicating decompressive surgery and instrumented mono-, bi- or trisegmental spondylodesis with posterior instrumented fusion system and an intervertebral cage (TLIF)
4. Unresponsive to non-operative treatment for a minimum of 3 months including at least physiotherapy, pain medication and local infiltration therapy
5. Presence of progressive symptoms or signs of nerve root and/or spinal cord compression although performing conservative treatment
6. Aged between 18 and 85 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Previous surgery: Any instrumented lumbar spinal surgery, cervical and/or thoracic spinal disease to the extent that surgical consideration is likely or anticipated within 6 months after the lumbar surgical treatment
2. Other degenerative joint diseases (i.e. shoulder, hip knee) to the extent that surgical consideration is likely or anticipated within 6 months after or before the lumbar surgical treatment
3. Any other physical diseases (e.g. neuromuscular disorders) before and/or within 6 months after lumbar surgical intervention which are able to restrict study procedures (i.e. wheelchair bound) or preclude accurate clinical examination or outcome
4. Adipositas, severe obesity (BMI > 35 kg/m2)
5. Neoplasia as the source of symptoms
6. Fixed or permanent neurological deficit unrelated to the lumbar spine disease
7. Active or chronic infection, systemic or local, including HIV, AIDS, Hepatitis
8. Active malignancy defined as a history of any invasive malignancy, except non-melanoma skin cancer, unless the patient has been treated with curative intent and there have been no clinical signs or symptoms of the malignancy for a minimum of 5 years
9. Autoimmune disorder that impacts the musculoskeletal system (i.e. lupus, rheumatoid arthritis, ankylosing spondylitis)
10. Acute episode or major mental illness (psychosis, major affective disorder or schizophrenia)
11. Physical symptoms without a diagnosable medical condition to account for the symptoms, which may indicate symptoms of psychological rather than physical origin
12. Recent or current history of substance abuse (drugs, alcohol, narcotics, recreational drugs)
13. Known allergy to titanium, Carbon/PEEK and tantalum or intolerance to any device material)

Date of first enrolment
01/01/2017

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Innsbruck
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Sponsor information

Organisation
Medical University of Innsbruck

ROR
https://ror.org/03pt86f80

Funder(s)

Funder type
Industry

Funder Name
DePuy Synthes (Johnson & Johnson Medial Products GmbH)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/02/2018		Yes	No