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Endoscopic discectomy versus microdiscectomy

Submission date
10/01/2012

Recruitment status
No longer recruiting

Registration date
08/03/2012

Overall study status
Completed

Last Edited
12/01/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
A herniated (prolapsed) disc occurs when parts of the disc bulge into the vertebral canal, causing pain. The back muscles tense simultaneously causing additional pain. Fortunately, most herniated discs do not require surgery. However, a very small percentage of people with herniated discs may experience severe low back pain which is mostly accompanied with pain that radiates into the leg and which significantly affects their daily life. The initial treatment for a herniated disc is usually conservative and non-surgical. The doctor may prescribe bed rest, or advise the patient to maintain a low, painless activity level for a few days to several weeks. This helps inflammation around the spinal nerves to decrease. A herniated disc is frequently treated with nonsteroidal anti-inflammatory medication and the doctor may recommend physical therapy. The therapist will perform an in-depth evaluation, which combined with the doctor's diagnosis, will dictate a treatment specifically designed for patients with herniated discs. The doctor may recommend surgery if conservative treatment options, such as physical therapy and medications, do not reduce or end the pain altogether. He or she will talk to the patient about the types of spinal surgery available, and depending on the specific case, will help to determine what procedure might be an appropriate treatment. The standard method of treatment of a prolapsed disc is microdiscectomy. This is an open procedure performed through a short incision (cut) of usually 3-5 cm. The nerve root is carefully moved out of the way and the prolapsed disc material removed. Generally patients do extremely well but there is some risk of scarring at the site of surgery. The surgery is done under a general anaesthetic. Endoscopic discectomy uses a different route of access to the spine. A cannula (hollow cylinder) is inserted and through this is passed an arthroscope (camera tube). The disc is visualized and the protruding piece removed. There is generally less scarring and a quicker recovery. The surgery is done under a local anaesthetic (with the patient sleepy but not asleep) or a weak general anaesthesia. The aim of this study is to find out which method is better in terms of result and which method has the lowest total costs, including also the patient's capacity to return to work if they are employed.

Who can participate?
Patients aged 25-55 with a disc prolapse of the lower lumbar spine

What does the study involve?
The study doctor asks the participant questions about their medical history, and they are asked to complete some questionnaires for the surgery and the study. Participants undergo a screening procedure. Participants are randomly allocated to undergo either endoscopic

discectomy (TESS) or microdiscectomy. Both procedures take the same length of time (about 60 min). Following the surgery participants are asked to complete future assessments forms to see how you feel (at 2 months, 1 year, 2 years and 5 years). All information is collected in an electronic database. Some questionnaires may be sent by e-mail. Participants have to fill out the electronic questionnaires and send them back. If they dont have an e-mail account or internet access, they either answer the questionnaires via phone interview, or receive the questionnaires in paper form by mail from the study centre. After filling out and sending back the questionnaires the data is held on a spreadsheet. Some anonymised data may be sent to the study sponsor for evaluation. If participants do not respond to their initial email they receive an additional email or mail and they are reminded to complete the questionnaires and return them.

What are the possible benefits and risks of taking part?
It is hoped that both procedures will help the participants. The risks are broadly similar and apply to all forms of spinal surgery. These will be outlined by the surgeon and a risk information sheet provided. The most serious is that of nerve root injury. There is a similar risk with both techniques (1%) but participants should be aware that any nerve injury is liable to be permanent. Nerve injury generally leads to a loss of power in the foot and numbness, but participants should be aware of the remote possibility of bladder paralysis (probably <0.1%). There are lesser risks of infections (antibiotics given) and tear to the lining of the spinal canal known as a dural leak. Both of these complications are usually easily treated, but a second surgical procedure might be required. The risks are similar with the two techniques. Superficial wound infections requiring a short course of antibiotics occurs in about 2% of people. With spinal surgery, the structure of the spine has to be disturbed to free trapped nerves or release pressure on the spinal cord and this may aggravate local spinal pain leading to discomfort from the wound after the operation. For most patients, this settles over a few days. The spine is visualized using x-rays during the surgery. Dosages are similar in the two procedures and no additional radiation is given by virtue of the study.

Where is the study run from?
The Royal Infirmary of Edinburgh (UK)

For how long is the study likely to run?
May 2006 to January 2015

Who is funding the study?
Lothian Health (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06/S1103/1

Study information

Scientific Title
A randomised controlled trial comparing transforaminal endoscopic discectomy with microdiscectomy

Study objectives
Null hypothesis: There is no difference in clinical outcomes following endoscopic or microdiscectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Service Lothian Research Ethics Committee, 13/03/2006, ref: 06/S1103/1

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.gibsonspine.eu/id6.html

Health condition(s) or problem(s) studied
Lumbar intervertebral disc

Interventions
Endoscopic surgery versus microdiscectomy

Microdiscectomy:
Open procedure through a short 5-8cm posterior spinal incision with general anaesthesia with overnight hospital admission.

Endoscopic discectomy:
An arthroscope (camera tube) is passed through a 7.5mm cannula inserted percutaneously with sedation plus local anaesthesia. Generally a day-case procedure.

The operating time is similar for both procedures at approximately 75 minutes.
Follow-up assessments at 2 months, 1, 2 and 5 years from surgery for both treatment arms.

Intervention Type
Procedure/Surgery

Primary outcome measure
Oswestry Disability Index

Secondary outcome measures
1. SF-36
2. Visual analogue pain scale
3. Coss

Overall study start date
03/05/2006

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Aged 25 - 55
2. Primary surgery
3. Single level disease, L3/4, L4/5, L5/S1
4. Evidence of nerve root compression
5. Failure of conservative treatment (6 weeks)

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Previous disc prolapse
2. Malignancy
3. Infective discitis
4. Weight >120 kg
5. Upper level disease
6. Massive disc prolapse
7. Intolerance of local anaesthesia

Date of first enrolment
03/05/2006

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
The Royal Infirmary of Edinburgh
Edinburgh
United Kingdom
EH16 4SU

Sponsor information

Organisation
Joimax GmbH (Germany)

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Sponsor type
Industry

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https://ror.org/032skq703

Funder(s)

Funder type
Industry

Funder Name
Joimax GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2017		Yes	No