(Cost) effectiveness of open Microdiscectomy vs. percutaneous transforaminal endoscopic discectomy (PTED) for patients with lumbosacral radicular syndrome due to a lumbar disc herniation

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Research question(s). There are two specific questions to be addressed:1) Is percutaneous transforaminal endoscopic discectomy (PTED) no worse in effectiveness than conventional unilateral open microdiscectomy for patients with symptomatic...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON55448

Source
ToetsingOnline

Brief title
PTED for LSRS (The PTED Trial)

Condition

- Joint disorders
- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
lumbar disc herniation; lumbosacral radicular syndrome; low back pain

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: VWS/ZonMw

Intervention

Keyword: Endoscopic surgery, Lumbar disc herniation, Lumbosacral radicular syndrome, Minimal invasive surgery

Outcome measures

Primary outcome

Primary outcome is: self-report leg pain (0-100 visual analogue scale (VAS))

which will be measured at various intervals throughout the year (the day

following treatment, 2, 4, and 6 weeks, 3, 6, 9, 12, 24 and 60 months).

Secondary outcome

Secondary outcomes: back pain (0-100 VAS), and functional status (Oswestry

Disability Index (ODI)), self-perceived recovery (single question measured on a

7-point Likert scale), quality of life (SF-36), patient satisfaction (single

question), health valuations (EQ-5D), and complications, such as re-operative

rate, or length of hospital stay. Patients will also receive a questionnaire at

24 months wherein the primary and secondary outcomes are measured with the

exception of direct and indirect costs. These measures, however, do not play a

role as primary endpoint.

Study description

Background summary

Lumbosacral radicular syndrome (LSRS) which is caused by a herniated lumbar nucleus pulposus (HNP) is a common problem with an annual incidence of 9 per 1000 persons (NHG Standard). The incidence increases in age and is the highest between 45 to 64 years of age (16 per 1000 persons annually). In The Netherlands, between 60,000 and 75,000 people develop LSRS annually. In 2009, ca. 11,000 herniated disc operations were performed in The Netherlands. Needless to say, the burden to society is tremendous, running in the millions in direct costs (Deyo 2006; Weinstein 2006) and in Nederland, is estimated to cost more than 1 billion euro due to direct and indirect costs, most notably due to production loss (Herniakliniek.nl).

The standard treatment for HNP's is open microdiscectomy. In recent years, a new surgical technique has been developed, namely percutaneous transforaminal endoscopic discectomy (PTED). PTED is a technique in which the hernia is removed through the foramen using a working shaft under endoscopic vision. The surgery is performed under local anaesthesia on an outpatient basis.

Suggested advantages of this technique include 1) less risk of nerve injury because the patient is treated under local anesthesia and can indicate to the surgeon if a nerve root has been damaged; 2) easier for obese patients; 3) less scarring; 4) less invasive and possibly more successful for those who have had an earlier operation because a different route is chosen; 5) patient is treated in the outpatient clinic and can return to home within hours following the procedure; 6) the procedure is quite successful for those with foraminal stenosis given that the foramen can be widened; and 7) particularly successful for those with foraminal and extra-foraminal HNP's which otherwise would be difficult to approach through the normal procedure. There are, however, disadvantages such as limited visibility whereby the chance of nerve root damage would occur. In addition, the chance of recurrent HNP's is larger because less discus material is removed during PTED. In general, numerous publications suggest that PTED is safe, that is to say, it has not been demonstrated that more complications occur with PTED than usual care (i.e. open microdiscectomy).

It is, however, questionable whether PTED is as effective or at least, no worse than the standard treatment (i.e. open microdiscectomy). The review by Kamper et al. (2013) identified three RCTs which examined the effect of PTED compared to microdiscectomy (Hermantin 1999; Krappel 2001; Mayer 1993). The results suggest that there is low to very low quality evidence that PTED is no better for back pain, leg pain, functional status, recovery, return-to-work or satisfaction at any follow-up moment. However, all three studies were small and of poor methodological quality, so strong conclusions cannot be drawn.

In recent years, the effect of PTED has been heatedly debated in The Netherlands. According to the Dutch Health Insurance Council (CVZ), an operative technique must meet certain requirements in order to be included in the public health insurance package. CVZ claims there is insufficient evidence

for PTED to be eligible for compensation. As a result, many patients were forced to pay the costs of treatment out-of-pocket and subsequently, filed a lawsuit. This issue has also appeared broadly and repeatedly in the media. A well-known example is the TV program RADAR, which discussed this topic in May 2012 on Dutch television (http://www.trosradar.nl/uitzending).

Study objective

Research question(s). There are two specific questions to be addressed:

1) Is percutaneous transforaminal endoscopic discectomy (PTED) no worse in effectiveness than conventional unilateral open microdiscectomy for patients with symptomatic lumbosacral radicular syndrome (LSRS)?
2) Which therapy (PTED or open microdiscectomy) is more cost-effective?

Study design

Research design: A pragmatic, multi-center non-inferiority RCT will be used. Following the baseline measurements wherein clinical and sociodemographic measurements are to be collected, patients are to be randomized to one of two groups: Group 1 will receive standard microdiscectomy (gold standard) and group 2 will receive PTED.

Once recruitment for the RCT has been completed, subjects will be recruited for an observational study from the same centra that participated in the RCT. The protocol to be followed will be exactly as the RCT. The reason for this aspect of the study is to collect more data on complications. These data will be collected from the patients* chart. Additionally, a form will be completed by the surgeon should a complication arise.

Intervention

Standard treatment (Open microdiscectomy)
Open microdiscectomy is to be conducted as follows: General or spinal anesthesia is to be administered. Verification is to be performed using a C-arm and the patient is to be positioned prone or in the salaam position. A paramedian incision is to be performed and the level is to be indicated. Loupe or microscope magnification is to be used. Laminotomy as well as foraminotomy is to be performed, if necessary. The amount of degenerative disc material to be removed is at the discretion of the attending surgeon. Post-operative policy will be followed and it is expected that the duration of recovery in the hospital may vary from 2-7 days, but the patient will be discharged as soon as medically responsible.

Intervention (Percutaneous Transforaminal Endoscopic Discectomy)
PTED is to be conducted as follows: Local anesthesia is to be administered.

Verification of the site to be performed by an image intensifier and depending upon the patient*s posture, a line is to be drawn from the center of the herniation. The needle is to be set and position checked. After the needle has reached the correct position, a guide wire is to be inserted. Following that, a series of conical rods are to be introduced. After drilling/reaming, in order to enlarge the neuroforamen, the instruments are to be removed, but the guide wire is to remain in place and the endoscope with the working channels are to be introduced via an 8mm cannula. The image intensifier ensures that the position of the cannula is maintained. Following removal of the hernia, the cannula and endoscope are removed. The patient is to be treated on an outpatient basis.

Study burden and risks

Based upon a recent, published systematic review conducted by our research group (Kamper et al. 2014), the two techniques are believed to be equivocal in both effectiveness and safety; therefore, it is believed that subjects randomized to the intervention (PTED) will not be put at any extra risk. In general, the risk associated with either procedures (intervention or control group) are thought to be negligible. Nevertheless, risk which might be attributed to the intervention (PTED) includes limited visibility whereby nerve root damage can occur; however, because the patient is awake during the procedure, the patient can indicate if a nerve root has been penetrated. In addition, there is the possibility of a recurrent hernia because too little disc material has been removed. Regardless, all the risks which occur will be registered. Possible benefits which might be ascribed to the intervention (PTED) include quicker recovery and return-to-work. The burden to the patients includes extra visits to the hospital which otherwise might not be necessary, in addition to the completion of questionnaires and a cost diary (for the economic evaluation).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• 18-70 years of age;
• > 16 weeks of persistent radicular irritation without motor or sensory loss in the leg
or > 6 weeks of radiating pain with- or without motor or sensory loss in the leg;
• indication for an operation according to consensus;
• MRI demonstrating lumbar disc herniation with nerve compression with or without concomitant spinal or lateral recess stenosis or sequestration;
• sufficient knowledge of the Dutch language in order to complete forms and follow instructions independently.

Exclusion criteria

• previous surgery on the same or adjacent disc level;
• cauda equina syndrome (CES);
• spondylytic or degenerative spondylolisthesis;
• pregnancy;
• severe comorbid medical or psychiatric disorder (ASA>2);
• severe caudal or cranial sequestration;
• moving abroad at short notice.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-02-2016
Enrollment:	682
Type:	Actual

Ethics review

Approved WMO Date:	09-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL50951.029.14