LIFT onderzoek

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24335

Source
NTR

Brief title
LIFT (Lumbar Interbody Fusion Trial)

Health condition

Lumbar fusion, degenerative disease lumbar spine, lumbar instability, spondylolisthesis, cost effectiveness, quality of life.

Lumbale fusie, degeneratieve lumbale wervelkolom, lumbale instabiliteit, spondylolisthesis, kosten effectiviteit, kwaliteit van leven.

Sponsors and support

Primary sponsor: Principal investigator: dr. Henk van Santbrink

Academisch fonds/Guy Peeters fonds - Academisch ziekenhuis Maastricht
Source(s) of monetary or material Support: Academisch fonds/Guy Peeters fonds - Academisch ziekenhuis Maastricht

Intervention

Outcome measures

Primary outcome

Reduction in disability measured by the change in Oswestry Disability Index (ODI) and changes in quality-adjusted life years (QALYs) measured with EQ-5D-DL.

Secondary outcome

Short Form (36) Health Survey, VAS back pain and leg pain, Hospital Anxiety Depression Scale (HADS), complications, productivity losses costs (iPCQ), medical costs (iMCQ), valuation of informal care (iVICQ)

Study description

Background summary

BACKGROUND
With a steep increase in the number of instrumented spinal fusion procedures, there is a need for comparative data to develop evidence based treatment recommendations. Currently, the available data on cost and clinical effectiveness of the two most frequently performed surgeries for lumbar spondylolisthesis, transforaminal lumbar interbody fusion (TLIF) and posterior lumbar interbody fusion (PLIF) is not sufficient. Therefore, current guidelines do not advise which is the most appropriate surgical treatment strategy for these patients. Non-randomized studies comparing TLIF and PLIF moreover suggest that TLIF is associated with fewer complications, less blood loss, shorter operative time and hospital duration. TLIF may therefore be more cost effective. The results of this study will provide knowledge on short- and long-term clinical and economical effects of TLIF and PLIF procedures, which will lead to recommendations for treating patients with lumbar spondylolisthesis.

METHODS
Multicenter blinded Randomized Controlled Trial (RCT; blinding for the patient and statistician, not for the clinician and researcher). A total of 144 patients over 18 years old with symptomatic single level lumbar degenerative, isthmic or iatrogenic spondylolisthesis whom are candidates for LIF (lumbar interbody fusion) surgery through a posterior approach will be randomly allocated to TLIF or PLIF. The study will consist of three parts: 1) a clinical effectiveness study, 2) a cost-effectiveness study, and 3) process evaluation.
The primary clinical outcome measure is: change in disability measured with Oswestry Disability Index (ODI) and change in quality adjusted life years (QALY) measured with EQ-5D-5L. Secondary clinical outcome measures are: Short Form Health Survey (SF-36), VAS back pain, VAS leg pain, Hospital Anxiety Depression Scale (HADS), complications, productivity related costs (iPCQ), medical costs (iMCQ) and valuation of informal care (iVICQ). Measurements will be carried out at five fixed time points (pre-operatively and at 3 months, 6 months, 12 months and 24 months).

DISCUSSION
It is hypothesized that TLIF, compared to PLIF, has similar clinical outcome in reducing disability. Moreover, direct medical costs are expected to be lower due to less surgical morbidity, shorter hospital stay and shorter surgical time. Indirect costs are assumed to be lower for TLIF as well, because we suspect less working days are lost. Currently, prospective data comparing cost-effectiveness of both techniques are not available. Therefore, in clinical practice both techniques are used and the choice for technique is greatly based on surgeon's preference. The demand for spinal fusion surgery has risen steeply over the last ten years and is expected to increase even further in the near future. As a result the burden on society (and the working population) will increase. In case our hypothesis is confirmed, treatment guidelines will be adapted, and TLIF will be recommended as first choice surgical treatment of lumbar spondylolisthesis. Ultimately this will lead to reduction of (direct and indirect) costs for spondylolisthesis patients eligible for instrumented spinal surgery.

Study objective

The hypothesis of the LIFT study is that TLIF is not inferior to PLIF in reducing disability in patients with single level spondylolisthesis, but that TLIF is more cost-effective when compared to the PLIF procedure.

Study design

All primary and secondary outcomes will be measured at five fixed time points: pre-operatively and at 3, 6, 12 and 24 months.

Except complications, only post-operatively at 3, 6, 12 and 24 months

Intervention

TLIF (transforaminal lumbar interbody fusion) or PLIF (posterior lumbar interbody fusion) (1:1 randomization).

Contacts

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Eligibility criteria

Inclusion criteria

- Indication for TLIF (transforaminal lumbar interbody fusion) of PLIF (posterior lumbar interbody fusion) surgery.

- Clinical mono uni-or bilateral lumbar radiculopathy or intermittent neurogenic claudication caused by a single level isthmic, degenerative or iatrogenic spondylolisthesis gr I, II or III according to Meyerding classification at level L3L4, L4L5 or L5S1.

- Age over 18 years.

- Single level spondylolisthesis with central or foraminal stenosis on MRI (or CT), of which the anatomical level is corresponding to the clinical syndrome.

- Psychosocially, mentally, and physically able to fully comply with this study protocol.

- Informed consent prior to this study.

Exclusion criteria

- Previous radiotherapy at the intended surgical level.

- (Progressive) motor failure and/or anal sphincter disorders which urges instant intervention.

- Active infection.

- Immature bone (ongoing growth).

- Active malignancy.

- Pregnancy.

- Symptomatic osteoporosis.

- Contra-indications for anaesthesia or surgery.

- Inadequate command of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
Enrollment:	160
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	30-03-2016
Application type:	First submission

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
NTR-new	NL5615
NTR-old	NTR5722
Other	METC-Zuyderland : 16T36

Study results