Lumbar Interbody Fusion Trial (LIFT): A randomized controlled multicenter trial for surgical treatment of lumbar spondylolisthesis.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON50249

Source
ToetsingOnline

Brief title
LIFT

Condition

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

Synonym
displacement of a lumbar vertebra, Spondylolisthesis

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

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

Outcome measures

Primary outcome

To determine change in Oswestry Disability Index. This can be obtained by completing the ODI-questionnaire pre- and postoperatively. This functional score is a tool for measuring patients permanent functional disability, specially designed for patients with low back related disabilities.
To determine change in quality of life adjusted years (QALY) with EQ-5D-5L, measured pre- and postoperatively. The EQ-5D-5L is a questionnaire to determine the quality-adjusted life years associated with a health state.

Secondary outcome

- Hospital Anxiety Depression Scale (HADS): To determine the pre-operative anxiety and depression level with the use of HADS, a fourteen item scale, consisting of a 7-item depression scale and a 7-anxiety scale. The score range from 0-21 with a high score being indicative for depression/anxiety.
- Short Form (36) Health Survey: To determine change in a patient-reported survey of patient health (physical and social status) consisting of 8 domains: Physical functioning, physical role functioning, emotional role functioning, vitality, mental health, social functioning, bodily pain and general health perceptions. Each domain is scored on a 0-100 scale, the higher the score the

less disability.

- Visual Analogue Scale (VAS) score of back pain and leg pain: To determine change in back and leg pain assessed on a horizontal 10 cm visual scale, varying from 0 cm (no pain) to 10 cm (worst pain imaginable).
- To compare the number and kind of complications (defined as; dural tear, postoperative infection, hematoma, hardware failure, neurological deficits, medical other complications as pneumonia or urinary tract infection) between both procedures, peri- and postoperatively.
- To determine clinical outcome by pre-operative and postoperative physical examination. Muscle strength of the legs classified with the MRC scale, sensibility in dermatomes classified into normally present, changed and absent, reflexes in the lower extremities.
- Cost effectivity of both procedures determined with productivity related costs(iPCQ) and medical costs(iMCQ).*

Study description

Background summary

Low back pain, with or without leg pain, is a common complaint in the general population. It causes disability and health care problems in the work force, and hereby a large economic burden on society. In the Netherlands back (and neck) complaints are responsible for 25% of health care costs for musculoskeletal disease (1.5% of total health care budget) (RIVM).

The lifetime prevalence of developing low back pain is 70%. The reporting of the prevalence of accompanying leg pain (sciatica) varies greatly with a range of 1.2-43%. In few cases these complaints are caused by lumbar spondylolisthesis (incidence of spondylolisthesis in adult population being approximately 6%). If conservative treatment, consisting of brace support, pain medication, physiotherapy or manual therapy fails, surgical treatment can be

considered.

The aim of surgery is to treat leg pain that is caused by compression or stretch of neurogenic structures. Instrumented spinal fusion is the preferred surgical treatment for these indications, and is more and more commonly used; in the US, between 1998 and 2008 the national bill for instrumented spinal fusion increased 7.9-fold. This increase is also expected in the Netherlands (RIVM). Currently XX surgical treatments are executed every year in the Netherlands.

Various instrumented spinal fusion techniques have been described; PLIF was introduced in 1953 by. TLIF is a modification of PLIF introduced. Over the years several other variations as ALIF, XLIF etc. have been developed, still for the same indications.

In case of isthmic spondylolisthesis, leg pain is generally caused by compression and stretch of the exiting nerve root at the isthmic level, uni- or bilaterally. In case of degenerative spondylolisthesis, leg symptoms are generally caused by compression of the cauda equina/nerve roots in the spinal canal resulting in neurogenic claudication (Syndrome of Verbiest). Surgery aims at decompressing neurogenic structures, by means of laminectomy of the proximal level involved in the listhesis. To prevent progression of listhesis decompression is accompanied by lumbar pedicle screw fixation and spinal fusion using interbody cage or cages.
The TLIF procedure consists of placement of one cage in the intervertebral space, using a unilateral approach at the side where nerve root complaints are most severe. Due to the *banana* shape of the cage, it can be placed in the midline and is assumed to decompress the contra-lateral nerve root as well. The PLIF procedure consists of placement two identical cages bilaterally in the intervertebral space using a bilateral approach.

Currently both techniques are world wide standard care. There are no strict indications for using either techniques, nor is literature (low-quality observational reports) in this matter conclusive. As a result the choice for technique is based on a surgeon*s experience and preference.

A number of cohort studies have shown that both methods effectively reduce leg pain. Non-randomized studies suggest that TLIF is associated with fewer complications, less blood loss, shorter surgical time and shorter hospital duration, perhaps related to unilateral, less invasive character of the procedure. These findings have not been confirmed in a randomized controlled trial (RCT).

Therefore TLIF should be the preferred technique of choice: 1. Surgical morbidity rates are in favor of TLIF, 2. Direct (surgical) costs for TLIF appear lower, 3. Indirect costs are in favor of TLIF, 4. Clinical outcome is effective for both techniques.

This study proposes to analyze in a high quality design (multicenter, patient blinded, randomized controlled trial) the cost-effectiveness of the TLIF technique compared to PLIF technique for patients with intermittent neurogenic claudication and/or mono uni-or bilateral lumbar radiculopathy caused by single level degenerative, isthmic or iatrogenic spondylolisthesis.

Study objective

Currently the available data on cost and clinical effectiveness of TLIF compared to PLIF for patients with lumbar spondylolisthesis is not sufficient. With a steep increase in instrumented spinal fusion, and an expected further increase in the future, there is a need for comparative data to develop evidence based treatment recommendations. The current guidelines do not advise which is the most appropriate surgical treatment strategy for these patients. The results of this study will provide surgical treatment recommendations for patients with lumbar spondylolisthesis and contribute to the understanding of its short- and long-term clinical postoperative course. *

Study design

Multicenter, patient blinded, randomized controlled trial.

Intervention

Transforaminal lumbar interbody fusion (TLIF) compared to posterior lumbar interbody fusion (PLIF).

Study burden and risks

All mentioned questionnaires are currently standard care for this surgical procedure in our hospital. Only the questionnaires for economical evaluation are additional. Patients are expected to invest 20 minutes per follow up moment extra for this (in total 5x over 2 years, pre-operatively, at 3 months, 6 months, 12 months and 24 months). The risks are standard risks associated with this surgical procedure, this is not research dependent.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Indication for TLIF (transforaminal lumbar interbody fusion) of PLIF (posterior lumbar interbody fusion) surgery.
2. 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.
3. Age over 18 years.
4. Single level spondylolisthesis with central or foraminal stenosis on MRI (or CT), of which the anatomical level is corresponding to the clinical syndrome.
5. Psychosocially, mentally, and physically able to fully comply with this study protocol.
6. Informed consent prior to this study., Inclusioncriteria of informal caregivers of patients:
1. The patient where the ICG offers his care, has to participate in the LIFT-study.
2. Age over 18 years
3. Psychosocially, mentally, and physically able to fully comply with this study protocol.
4. Informed consent prior to this study.

Exclusion criteria

1. Previous radiotherapy at the intended surgical level.
2. (Progressive) motor failure and/or anal sphincter disorders which urges instant intervention.
3. Active spinal infection.
4. Immature bone (on-going growth).
5. Active malignancy.
6. Pregnancy.
7. Symptomatic osteoporosis (based on DEXA-scan).
8. Contra-indications for anaesthesia or surgery.
9. Inadequate command of the Dutch language., Exclusioncriteria of informal caregivers of patients:
1. Inadequate command of the Dutch language.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-09-2017
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	31-03-2016
Application type:	First submission
Review commission:	METC Atrium-Orbis-Zuyd

Approved WMO Date:	15-08-2017
Application type:	Amendment
Review commission:	METC Atrium-Orbis-Zuyd
Approved WMO Date:	01-11-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	22-07-2019
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	12-03-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL54717.096.16