Clinical outcome and adjacent segment disease 5 and 10 years after posterior and anterior fusion for low grade isthmic spondylolisthesis

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To determine the incidence of radiological adjacent segment pathology (RASP) at 5 and 10 years after posterior and anterior fusion performed for low grade L5-S1 isthmic spondylolisthesis, and to evaluate the clinical outcome.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON42432

Source
ToetsingOnline

Brief title
SLIPS 5-10y

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Isthmic slip; slipped vertebra

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Stichting OrthoResearch

Intervention

Keyword: Adjacent Segment Pathology, Isthmic spondylolisthesis

Outcome measures

Primary outcome

The main outcome parameter is the incidence of RASP evaluated using magnetic resonance imaging (MRI) and scored according to the Pfirrmann criteria. An MRI of the lumbar spine will be obtained to evaluate adjacent levels for radiological disc and facet joint degeneration. FJOA will be classified according to Kettler and Weishaupt and the Pfirrman score will be used as a grading system for the assessment of lumbar intervertebral disc degeneration. A 3.0 T Philips MRI scanner (Philips Medical Systems, Best, The Netherlands) is used for radiological evaluation.

Secondary outcome

The secondary study parameters are the clinical and radiological outcomes up to 10 years postoperatively.

Clinical outcomes as scored on:

* VAS back and leg pain

* VAS satisfaction

* ODI-score

* SF-36

* EQ-5d

* Device-related complications

Radiological outcomes as scored on:

* Sagittal alignment (standing XLSWK lateral hips and full spine lateral

including hips)

Tertiary study parameter: The correlation between RASP (FJOA and lumbar

intervertebral disc degeneration) and the secondary outcome parameter CASP.

When VAS *50 and ODI *43, we will classified this as CASP.

Study description

Background summary

Specific treatment for isthmic spondylolisthesis is still not completely clarified. The goal of surgical intervention is to achieve pain reduction by a solid fusion between the vertebrae affected. This fusion can be achieved through a posterior, anterior, or combined approach. Supplementary instrumentation, decompression, or reposition of the listhesis can be considered. The surgical approach used in the Sint Maartenskliniek is the circumferential approach, which means a combination of an anterior interbody fusion with posterior reduction and pedicle screws performed in two separate procedures.

The role of sagittal alignment and the related possible benefits of reduction (and therefore also instrumentation) of the listhesis have not been adequately studied. Therefore it is still impossible to determine the optimum surgical treatment technique since there is limited data concerning long term benefits of circumferential fusion and the development of MRI proven Radiological Adjacent Pathology (RASP) or Clinical Adjacent Pathology (CASP). This information is immensely important, as findings could help to make the circumferential an good an evidence-based accepted technique for the surgical treatment of low-grade isthmic spondylolisthesis.

Study objective

To determine the incidence of radiological adjacent segment pathology (RASP) at 5 and 10 years after posterior and anterior fusion performed for low grade L5-S1 isthmic spondylolisthesis, and to evaluate the clinical outcome.

Study design

Long term follow-up (5 and 10 years) of a prospective consecutive single institution patient cohort who underwent a combination of an anterior interbody fusion followed by a posterior decompression in two separate procedures.

Study burden and risks

The follow-up protocol is extended to 5 and 10 years follow-up post-operative. The extra amount of time over the 5 years that a patient invests in the study is about 2 times 90 minutes. Patients participating in this study will not being barred by any additional risk. The questionnaires do not bring any extra burden. The additional radiological assessments (full spine X-ray at 5 and 10 years follow-up) increases the total amount of radiation only slightly. However, the total amount of radiation falls within the limits of the ICRP (International Commission of Radiological Protection).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The current studie concerns a long term follow-up (5 and 10 years) of a existing prospective consecutive single institution patient cohort who underwent a circumferential fusion.
;Patients were included with:;- A single level, low-grade, isthmic spondylolisthesis between L5 and S1, qualifying for fusion of that single level
- Chronic low back pain with our without leg-pain
- Failure of conservative treatment for more than 6 months
- Age >21 years
- Signed informed consent

Exclusion criteria

- Previous attempted fusion at that lumbar level
- Metabolic bone disease
- Active systemic infection
- Patient has physical, emotional or neurological conditions that would compromise the patient's compliance with postoperative rehabilitation and follow-up (e.g.: drug or alcohol abuse, serious mental illness, or general neurological conditions such as Parkinson, Multiple sclerosis, etc.).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2016

Enrollment:	43
Type:	Actual

Ethics review

Approved WMO Date:	28-09-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL54964.048.15