The Sciatica - Gill Trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27610

Source
NTR

Brief title
N/A

Health condition

spondylolytic spondylolisthesis; decompression; spondylodesis; sciatica.

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Industrial sponsoring

Intervention

Outcome measures

Primary outcome

The primary outcome measure is an illness-specific 23 item functional assessment questionnaire; the Roland Disability Questionnaire for Sciatica.

Secondary outcome

Secundary outcome measures are:
Horizontal 100mm Visual Analoge Scale (VAS) for legpain and backpain, perceived recovery

on the 7-point Likert scale adjusted to job and hobby, functional outcome of the patient by the surgeon using the Macnab classification, work experience according to the Karasek Job Content Questionnaire, emotional status of the patient determined by the Hospital Anxiety Depression Scale (HADS), quality of life according to a generic health status questionnaire SF-36, Quality-Adjusted-Lifeyears (QALY) based on EuroQol, serum level creatine phosphokinase (CPK) , dynamic X-ray of the lumbar spine, complications and re-operation incidence.
The economic evaluation will compare differences in societal costs to differences in the primary outcome measure (NDI) and in quality adjusted life years (QALYs). In the primary analysis QALYs will be calculated from the EQ-5D, in secondary analyses also from the SF-6D and VAS. Sensitivity analyses will be performed on the intervention costs, societal versus health care perspective, and the applied utility measure (EQ-5D, SF-6D or VAS). A time-horizon of 5 years will be used, with discounting for both costs and QALYs.

Study description

Background summary

Spondylolytic spondylolisthesis is an anterior slip of one verebral body on to another caused by a disconnection of the pars interarticularis of the arch. Patients present with radicular pain or neurogenic claudication with or without backpain caused by nerve root compression underneath the newly formed pseudojoint, or compression in the foramen between pedicle and slipped disc. Surgical treatment consists of excision of the pseudojoint (nerveroot decompression according to Gill) mostly in combination with instrumented fusion. Instrumented spondylodesis is major surgery with a substantial complication rate and it's necessity has not been proven. Nerve root decompression according to Gill is a less invasive procedure with short hospitalisation, quick mobilisation and fast resumption of daily activities. Therefore, we postulate that Gill's procedure is more cost-effective on the short term (12 weeks) and at least equal cost-effective on the long term (2 years).

Study objective

The trial concentrate on the question is a instrumented fusion in the treatment of spondylolytic spondylisthesis (cost) effectiveness than a decomporession according to Gill, both in short and long term.

Study design

Follow up of all patients will be performed at 6, 12, 26, 52, 104 and 260 after surgery.

Questions will be send by mail.

Intervention

Patients present with radicular pain or neurogenic claudication with or without backpain caused by nerve root compression underneath the newly formed pseudojoint, or compression in the foramen between pedicle and slip disc. Surgical treatment consists of excision of the pseudojoint:

Group A: Nerveroot decompression according to Gill

Group B: Nerveroot decompression acoording to Gill in combination with instrumented fusion.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-70 years

2. Low grade spondylolytic spondylolisthesis (grade I or II)

3. Sciatica or neurogenic claudication with or without backpain

4. Symptoms lasting more than 3 months.

5. Inform consent

Exclusion criteria

1.High grade spondylolytic spondylolisthesis (grade III or IV)

2. Backpain only

3. Progressive spondylolisthesis

4. Abnormal mobility X-ray (> 3mm)

5. Previous lumbar surgery at level of spondylolusthesis

6. Severe comorbidity / contra-indication surgery

7. Planned (e)migration in the year after surgery

8. Inadequate knowledge of Dutch language

9. Pregnancy

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-05-2008
Enrollment:	220
Type:	Actual

Ethics review

Positive opinion Date:	28-04-2008
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	NL1254
NTR-old	NTR1300
Other	METC LUMC : P08.010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A