

The Sciatica - Gill Trial

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27610

Bron

NTR

Verkorte titel

N/A

Aandoening

spondylolytic spondylolisthesis; decompression; spondylodesis; sciatica.

Ondersteuning

Primaire sponsor: Leids Universitair Medisch Centrum

Overige ondersteuning: Industrial sponsoring

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Spondylolytic spondylolisthesis is an anterior slip of one vertebral 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 its 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).

Doel van het onderzoek

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

Onderzoeksopzet

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

Questions will be send by mail.

Onderzoeksproduct en/of interventie

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 according to Gill in combination with instrumented fusion.

Contactpersonen

Publiek

LUMC, afdeling neurochirurgie

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 spondylolisthesis
6. Severe comorbidity / contra-indication surgery
7. Planned (e)migration in the year after surgery
8. Inadequate knowledge of Dutch language
9. Pregnancy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2008
Aantal proefpersonen:	220
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	28-04-2008

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1254
NTR-old	NTR1300
Ander register	METC LUMC : P08.010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A