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# A multicentre randomised cost-effectiveness trial concerning the timing of surgery for sciatica caused by a lumbar disc herniation

**Submission date**
02/07/2003

**Recruitment status**
No longer recruiting

**Registration date**
07/08/2003

**Overall study status**
Completed

**Last Edited**
24/07/2015

**Condition category**
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

945-02-035

# Study information

### Scientific Title
A multicentre randomised cost-effectiveness trial concerning the timing of surgery for sciatica caused by a lumbar disc herniation

### Acronym
The Sciatica Trial

### Study objectives
Lumbar disc surgery is often performed in patients who have sciatica that does not resolve within six weeks, but the optimal timing of surgery is not known. Guidelines advise to discuss surgery with patients after six weeks of sciatica. This statement is not scientifically based and investigated by the current randomised controlled trial (RCT).

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Medical Ethics Committee of Leiden University Medical Center, 20/12/2001, ref: P178/98

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Severe sciatica caused by a lumbar disc herniation with root compression

### Interventions
1. Surgery as soon as possible and within two weeks after randomisation
2. Prolonged conservative treatment by the General Practitioner. If natural history leads to aggravation of sciatica or does not result in some recovery 6 months after randomisation, 'late surgery' will be performed

### Intervention Type

Procedure/Surgery

### Primary outcome measure
1. Roland Disability Questionnaire
2. Visual Analogue Scale (VAS) leg pain
3. Global perceived recovery during the first year after randomisation

### Secondary outcome measures
1. 36-item Short Form health survey
2. VAS back pain
3. Sciatica frequency and bothersomeness index
4. PROLO scale

### Overall study start date
15/11/2002

### Completion date
28/02/2005

## Eligibility

### Key inclusion criteria
Patients (18 - 65 years old) with at least 6 weeks and a maximum of 12 weeks sciatica not reacting to conservative treatment. An indication for surgery is made by the clinical picture with magnetic resonance imaging (MRI) confirmation of a lumbar disc herniation.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
280 were necessary, 283 were included

### Key exclusion criteria
1. Cauda equina syndrome
2. Severe paresis (MRC less than 3)
3. Identical complaints in the past twelve months
4. A history of spine surgery, bony stenosis, spondylolisthesis
5. Pregnancy
6. Severe comorbidity

### Date of first enrolment

15/11/2002

**Date of final enrolment**
28/02/2005

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Leiden University Medical Center**
Leiden
Netherlands
2333 ZA

# Sponsor information

**Organisation**
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

**Sponsor details**
Laan van Nieuw Oost Indie 334
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**Sponsor type**
Research organisation

**ROR**
https://ror.org/01yaj9a77

# Funder(s)

**Funder type**
Research organisation

**Funder Name**

Netherlands Organisation for Health Research and Development

### Alternative Name(s)
Netherlands Organisation for Health Research and Development

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Other non-profit organizations

### Location
Netherlands

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 11/02/2005 | | Yes | No |
| Results article | results | 31/05/2007 | | Yes | No |
| Results article | results | 10/11/2007 | | Yes | No |
| Other publications | cost-utility analysis | 14/06/2008 | | Yes | No |
| Results article | results | 14/06/2008 | | Yes | No |
| Results article | results | 14/03/2013 | | Yes | No |
| Results article | results | 01/12/2013 | | Yes | No |
| Results article | results | 29/10/2014 | | Yes | No |