

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

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Registration date 07/08/2003	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 24/07/2015	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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?
Results article	results	31/05/2007		Yes	No
Results article	results	10/11/2007		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
Protocol article	protocol	11/02/2005	Yes	No
Other publications	cost-utility analysis	14/06/2008	Yes	No