

Surgery versus conservative care for lumbar disc herniation

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
26/03/2009	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
10/08/2009	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
11/07/2019	Digestive System	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Heikki Österman

Contact details

Tenholantie 10
Helsinki
Finland
00280

-
heikki.osterman@orton.fi

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Effectiveness of microdiscectomy for lumbar disc herniation: a randomised controlled trial

Acronym

Iskari

Study objectives

Evidence on the best management of sciatica of 6 to 12 weeks' duration is limited. Surgical patients seem to have a more rapid recovery in the very short term, but the effectiveness of surgical management in mid- and long-term is unclear.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Boards of Jorvi Hospital and University Hospitals of Tampere, Kupio and Oulu approved in Autumn 1996

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lumbar disc herniation

Interventions

Lumbar microdiscectomy versus continued non-surgical care. The non-surgical group was intended to mimic the natural course of healing of disc herniation, thus there was no specific program. The patients were encouraged to do isometric muscle exercises and walk right from the start; passive forms of treatment were discouraged. Treatment in the operative arm involved having a disc operation and a period of convalescence after that. Duration of treatment in that sense was about six weeks.

Duration of treatment can be estimated at six weeks, after that the study involved observation only. Follow-up of both arms is planned to last ten years, 2- and 6-year results have been assessed (2-year results published).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Leg pain (Visual Analogue Scale [VAS]). Assessed 6 weeks, 3 months, 6 months, 1 year, 2 years and 6 years post randomisation. A ten-year follow-up will take place in due course.

Key secondary outcome(s)

1. Back pain (VAS)
2. Recovery of working ability (VAS)
3. Satisfaction with treatment (VAS)

4. Disability associated with back pain (Oswestry index)
5. Self-assessed global recovery (Likert scale 0 - 6)
6. Physical findings

Assessed 6 weeks, 3 months, 6 months, 1 year, 2 years and 6 years post randomisation. A ten-year follow-up will take place in due course.

Completion date

31/12/1999

Eligibility

Key inclusion criteria

1. Aged 20 to 50 years, either sex
2. Sciatic pain of 6 - 12 weeks' duration
3. Sciatica below knee and at least one physical finding suggestive of nerve root involvement
4. Computed tomography (CT) verified disc extrusion or sequester compatible with the clinical symptoms and findings

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

56

Key exclusion criteria

1. Spontaneous resolution of sciatic symptoms during a minimum follow-up of two weeks
2. Sick leave of more than three months' duration preceding randomisation
3. Spondylolisthesis
4. Symptomatic spinal stenosis
5. Previous spine surgery
6. Pregnancy
7. Major medical or post-traumatic conditions confounding the assessment of effectiveness of treatment
8. Mental or behavioural disorder jeopardising the attachment to the trial protocol

Date of first enrolment

01/01/1997

Date of final enrolment

31/12/1999

Locations

Countries of recruitment

Finland

Study participating centre

Tenholantie 10
Helsinki
Finland
00280

Sponsor information

Organisation

Finnish Centre for Welfare and Health (Finland)

ROR

<https://ror.org/03tf0c761>

Funder(s)

Funder type

Government

Funder Name

Finnish Centre for Welfare and Health (Finland) - funding in the planning phase of the study

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	01/10/2006	11/07/2019	Yes	No