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Surgery versus conservative care for lumbar disc herniation

Submission date	Recruitment status	[_] Prospectively registered
26/03/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/08/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/07/2019	Digestive System	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/1997

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

Age group
Adult

Sex
Both

Target number of participants
56

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
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00280

Sponsor information

Organisation
Finnish Centre for Welfare and Health (Finland)

Sponsor details
P.O. Box 30
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Sponsor type
Government

Website

http://www.thl.fi

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

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?
Results article	results	01/10/2006	11/07/2019	Yes	No