

Revalideren na een lumbale hernia operatie.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23258

Source

NTR

Brief title

REALISE

Health condition

lumbar disc surgery

Sponsors and support

Primary sponsor: VU University Amsterdam

Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

1. Global perceived recovery (7-point scale);
2. Functional status (Oswestry Disability Index (ODI));
3. Pain intensity (leg and back) (11-point NRS);

4. General health (SF-12);
5. Quality of life (EuroQol);
6. Costs of production losses (Prodisq).

Secondary outcome

-

Study description

Background summary

In the Netherlands there are two strategies for rehabilitation of patients following lumbar disc surgery. In some hospitals rehabilitation is restricted to the hospital phase and after discharge there is no more supervised rehabilitation. However, there are also hospitals that continue rehabilitation directly after discharge, during the first 6 weeks after surgery. This rehabilitation is mainly delivered by PTs in a primary care setting. Since January 1st, 2006, patients can also directly access PT without a referral (DTF). Then the PT has to decide after initial assessment if rehabilitation is indicated and some PTs opt for continuation of the rehabilitation while others don't. So, regardless of the specific procedure (referral by neurosurgeon or DTF) there is wide variation in care. This project will provide an answer to the question whether rehabilitation should be started directly after discharge from the hospital or not, and will guide evidence-based decision making for patients who undergo lumbar disc surgery.

Study objective

N/A

Study design

Measurements will take place at baseline and after 3, 6, 9, 12 and 26 weeks.

Intervention

Intervention group: Physiotherapy directly after discharge. Patients receive instructions and information regarding appropriate 'use of body mechanics' for the whole body and will be taught back protection methods. Depending on a clinical assessment the rehabilitation program will focus on relaxation positions and techniques, stretching exercises in order to increase soft tissue flexibility and joint mobility, and/or stabilizing and strengthening exercises (as tolerated by the patient). Patients will receive a home exercise program as well.

The aim is that there will be 6 treatment sessions within the first 6 weeks after discharge from the hospital 6 weeks, but the exact number of sessions is at the discretion of the therapist. After these 6 weeks the patient visits the neurosurgeon, which is customary in the participating hospitals (and in the majority of the hospitals in the Netherlands as well). At the six weeks consultation the neurosurgeons decides whether continuation of therapy is necessary.

Control group: No treatment during 6 weeks after discharge. Also in this group the patient visits the neurosurgeon after 6 weeks. At the six weeks consultation the neurosurgeons decides whether the patient still should be referred to therapy or not.

Contacts

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Eligibility criteria

Inclusion criteria

Patients who underwent a first time, single level lumbar discectomy, aged between 18-69 years.

Exclusion criteria

Co-morbidities of the lumbar spine (e.g., fractures, carcinomas osteoporosis), cauda equina

syndrome. Furthermore patients who are pregnant and patients with general contraindications for exercise therapy will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion	
Date:	18-11-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3008
NTR-old	NTR3156
Other	ZonMW / METC : 80-82310-97-11043 / NL35897.029.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A