Rehabilitation following lumbar disc surgery

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To assess if a continued rehabilitation program in the first six weeks post-surgery for patients following a first time is morecost-effective as compared to no further treatment after discharge from the hospital an economic evaluation alongside...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON41704

Source
ToetsingOnline

Brief title
Rehabilitation following lumbar disc surgery

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
Low back pain post surgery

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: - lumbar disc surgery, - Physiotherapy, - Randomised controlled trial, - Rehabilitation

Outcome measures

Primary outcome

Primary outcomes are: global perceived recovery (7-point scale), functional status (Oswestry Disability Index (ODI)), and pain intensity (leg and back) (11-point NRS).

Qualitative study: factors related to treatment adherence.

Secondary outcome

Also general health (SF-36) return to work and quality of life (EuroQol) are measured. Costs will be recorded in cost diaries. Timing of measurement: baseline (in addition to outcomes at baseline also demographics and most important prognostic factors are measured), 3, 6 and 26 weeks.

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. If complaints persist at the 6 weeks consultation of the neurosurgeon, a patient is referred for physiotherapy (PT). 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. Evidence shows that continuation of rehabilitation within the first 6 weeks is effective and leads to faster recovery but a head-to-head comparison of the cost-effectiveness is lacking.

Adherence to the exercise program and advice is expected to influence the effectiveness of the provided exercise therapy. Adherence to this treatment can be defined as the extent to which a patient follows recommendations from the healthcare professional who provides the exercise therapy. However, exercising happens to be the most common behaviour patients with pain fail to adhere to. Also adherence to physical activity or following advice is problematic. It is unclear which factors play a role in adherence to home exercises and advice in people who underwent surgery for lumbar disc herniation.

Study objective

To assess if a continued rehabilitation program in the first six weeks post-surgery for patients following a first time is more cost-effective as compared to no further treatment after discharge from the hospital an economic evaluation alongside a randomized controlled trial will be conducted.

The research question of the qualitative study is: what are the experiences of patients, who underwent lumbar disc surgery, with performing home exercises and following advice, and which factors play a role in adherence to these home exercises and advice? Insight into these factors is important, because it can contribute to the development of strategies that enhance adherence to home exercises and thus it can increase the quality of care for patients who underwent lumbar disc surgery.

Study design

An economic evaluation alongside a randomized controlled trial will be conducted.

The qualitative study uses a phenomenological framework. Semi-structured interviews will be used to investigate experiences of patients with aspects of post-operative exercise therapy.

Intervention

Patients are randomised into 2 groups:

1) In the continued rehabilitation group patients will receive treatment according to standardised treatment protocol.

2) Patients in the control group receive no further treatment after hospital discharge.

In both treatment groups, according to usual care, the neurosurgeon will decide together with the patient at the 6 weeks consultation if a patient is referred for physiotherapy (PT).

Study burden and risks

In the Netherlands there are currently two ways of rehabilitation after lumbar disc surgery: referral or no referral to a physiotherapist after discharge from hospital. In our study we do not deviate from the daily practice. In both treatment groups patients, after about 6 weeks, will visit the neurosurgeon for a consultation. If the patient has serious complaints a referral for physiotherapy is indicated, which in this study is also allowed. In short, we do not deviate from the usual care. Therefore there is no risk to participants for taking part in this study.

The only extra burden for patients is that they have to complete some questionnaires. This outweighs by far the undesirable variation in care at this moment. In the current situation decision making regarding the continuation of rehabilitation following lumbar disc surgery is mainly opinion-driven and not evidence-based. 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.

The participants in the qualitative study are only interviewed once, without being asked burdensome questions. This outweighs the current situation of possibly limited effects of post-surgery interventions due to low adherence and insufficient insight into factors related to low adherence.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion Criteria are: patients who underwent a first time, singe level lumbar discectomy and aged between 18-69 years. ;Inclusion criteria for the qualitative part: having received the intervenion in the randomised trial.

Exclusion criteria

Co-morbidities of the lumbar spine (eg. fractures, carcinoma*s osteoporosis, etc) Also patients with cauda equina syndrome will be excluded. Furthermore patients that are pregnant and patients with general contra-indications for exercise therapy will be excluded.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-05-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-12-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-04-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-03-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL35897.029.11