Revalideren na een lumbale hernia operatie.

Gepubliceerd: 18-11-2011 Laatst bijgewerkt: 18-08-2022

N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23258

Bron
NTR

Verkorte titel
REALISE

Aandoening

lumbar disc surgery

Ondersteuning

Primaire sponsor: VU University Amsterdam
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

N/A

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-11-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A