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A clinical trial to evaluate the influence of electrical stimulation on sensory and motoric deficits in patients with lumbar disc herniation

Submission date
01/12/2016

Recruitment status
No longer recruiting

Registration date
15/01/2017

Overall study status
Completed

Last Edited
28/11/2017

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Long-term back pain is one of the most common medical conditions among the adult population in the developed world. Studies have shown that up to 85% of German adults suffer from severe back pain at some point in their lives. Intervertebral disc degeneration is one of the most common causes of long-term low back pain. It is a serious condition that involves the breakdown of the small discs that lie between the vertebrae of the spine (intervertebral discs). It is often treated using a type of surgery called lumbar sequestrectomy, in which involves the removal of the damaged discs. However factors relevant for time and quality of recovery, of the surgical procedure, relative to conservative treatment, remain controversial and require further investigation. Surface electrical stimulation (SES) is being investigated as a new treatment option for pain relief. The way that this treatment works however and whether it is as effective as surgery is still not known however. The aim of this study is to evaluate the effectiveness of treatment by surface electrical stimulation (SES).

Who can participate?
Adults with long-term back pain caused by Iintervertebral disc degeneration who are going to be treated with surgery and adults with long-term back pain caused by Iintervertebral disc degeneration who are going to be treated using non-surgical techniques.

What does the study involve?
The first group of patients (those who are being treated using surgery), after undergoing surgery to remove the damaged discs in their back, are randomly allocated to one of two groups. Those in the first group receive one hour of SES per day for eight weeks. This involves attaching electrodes (sticky pads that conduct electricity) around the affected area and applying a mild electrical current. Those in the second group receive usual care after surgery only. Participants undergo a number of assessments to see how well they can sense cold and to assess their pain levels and quality of life at the start of the study and then again after 1 week, and then 2, 6, 12 and 24 months after surgery.
The second group of patients (those being treated using non-surgical techniques) receive treatment which may involve physical therapy and pain medication. They are randomly allocated

to one of two groups, the first of which receives one hour of SES per day for eight weeks, and the second who receive normal care alone. Participants undergo a number of assessments to see how well they can sense cold and to assess their pain levels and quality of life at the start of the study and then again after 1 week, and then 2, 6, 12 and 24 months.

What are the possible benefits and risks of participating?
There are no known risks involved with participating in this study.

Where is the study run from?
Medical University Hospital Innsbruck (Austria)

When is the study starting and how long is it expected to run for?
April 2016 to March 2022

Who is funding the study?
Medical University of Innsbruck (Austria)

Who is the main contact?
Miss Sara Lener

Contact information

Type(s)
Scientific

Contact name
Miss Sara Lener

Contact details
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Additional identifiers

Protocol serial number
1.1

Study information

Scientific Title
A prospective clinical trial to evaluate the influence of surface EMG-triggered multichannel electrical stimulation on sensomotoric recovery in patients with lumbar disc herniation

Acronym
RECO

Study objectives

There is a difference in cold detection threshold (CDT) after the use of electrical stimulation after 24 months of follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective single centre descriptive randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lumbar disc herniation

Interventions
Two patient populations are being included in this study. Population 1 includes patients who are being surgically treated, and Population 2 includes patients who are being conservatively treated.

Population 1:
Participants in this group are being treated with a lumbar sequestrectomy procedure. This takes place after induction of general endotracheal anesthesia and with the assistance of an operating microscope, while the patient is in a prone position. Surgery is performed by two trial designated surgeons in a standardized manner. The spinal canal harbouring the sequestrated disc material is exposed by performing a minimal inter-laminar fenestration to avoid removal of bone and articular structures. Based on results of a previous trial, only the herniated material is removed. The herniated space is not entered whenever possible.

Group 1: Participants receive 1 hour of surface electrical stimulation for the following 8 weeks of rehabilitation after they have undergone surgery. Patients are trained by the clinical investigator (s) at the study site to ensure proper usage of the stimulation device. Patients are then requested to perform treatment at home. Five electrodes (4x6.4cm PALS latex free neurostimulation electrodes, model 896230) are placed on the skin in the affected nerve root distribution area L3 to S1, according to instructions documented in the patient's individual manual. The stimulation device (STIWELL med4, MED-EL) is started and the pre-set program is chosen. The intensity will be increased until the patient feels a strong but comfortable tingling sensation and/or muscle contraction. If sensory or motor habituation appears, patients are instructed to increase the intensity until the comfortable tingling sensation and/or muscle contraction can be felt again. EMG-triggers are imparted over the devices' display and clearly signal the patient when to actively tense her/his muscles and when to pause. Patients are instructed to perform this treatment for one hour daily (2 x 30min) for the following 8 weeks. Time, date and duration of each treatment should be noted in a provided document and handed out to the investigators at the next follow-up. Furthermore, treatment time and duration can be read directly from the device to asssess the patient's compliance. If the treatment is found to be

uncomfortable or skin irritation appears, patients are asked to immediately contact the clinical investigators.

Group 2: Participants do not receive any additional treatment following surgery and receive standard follow up care only.

Participants in both groups are followed up 1 week, and then 2, 6, 12 and 24 months after surgery later by the clinical investigators.

Population 2:
Participants in this group are being treated using conservative methods, which involves pain medication, muscle relaxants, periradicular infiltration (if needed), physical therapy etc.

Group 1: Participants receive 1 hour of surface electrical stimulation for the 8 weeks. This follows the same procedure as in population 1.

Group 2: Participants do not receive any additional treatment and receive the standardized conservative methods (see above) and no extra electrical stimulation.

Participants in both groups are followed up after 1 week, and then 2,6, 12 and 24 months by the clinical investigators.

Intervention Type
Device

Primary outcome(s)
Cold detection threshold (CDT) is measured using the standardised quantitative sensory testing protocol at 24 months of follow-up.

Key secondary outcome(s))
1. Pain, back specific function, work disability and patient's satisfaction are measured using the Oswestry Disability Index (ODI) and the Core Outcome Measures Index (COMI) at baseline, within 1 week, 2, 6, 12 and 24 months
2. Generic health status (mobility, self-care, usual activities, pain/discomfort and anxiety /depression) is measured using EuroQoL-5Dimension (EQ-5D) at baseline, within 1 week, 2, 6, 12 and 24 months
3. Severity of depression and responsiveness to treatment is measured using the Beck Depression Inventory (BDI) at baseline, within 1 week, 2, 6, 12 and 24 months
4. Neuropathic pain components in patient with back pain are measured using the painDETECT questionnaire (PD-Q) at baseline, within 1 week, 2, 6, 12 and 24 months
5. Neurological status and the quality and quantity of current pain medication, including epidural injections and nerve block injections, are documented at baseline, within 1 week, 2, 6, 12 and 24 months
6. Sensory function is measured by Two-point-discrimination (2PD) at baseline, within 1 week, 2, 6, 12 and 24 months
7. Functionality is measured using the timed up and go test (TUG) at baseline, within 1 week, 2, 6, 12 and 24 months
8. Muscle force is tested by a manual muscle tester (MMT) at baseline, within 1 week, 2, 6, 12 and 24 months
9. Intraoperative problems such as surgery related- or device related complications and postoperative complications like re-operations, recurrent disc herniations, infection or bleeding

are recorded continuously throughout the study period
10. Characteristics of disc herniation and sagittal alignment are measured using magnetic resonance imaging (MRI) at baseline, within 1 week, 2, 6, 12 and 24 months
11. Cytokinelevels and inflammation markers are measured using IL-6, IL-1b, TNFa, CRP and WBC at baseline, within 1 week, 2, 6, 12 and 24 months

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Population 1 – Patients being operatively treated
1. Patients with a lumbar disc herniation causing sensomotoric dysfunction in nerve root distribution areas L3 to S1
2. Unresponsive to non-operative treatment for six weeks or presence of progressive symptoms or significant motor deficit or signs of nerve root compression in the face of conservative treatment
3. An indication for surgical treatment according to the guidelines of DGNC and DGOOC
4. MRI determined pathology at treatment level that correlates to primary symptoms

Population 2 – Patients being conservatively treated
1. Patients with a lumbar disc herniation causing sensomotoric dysfunction in nerve root distribution area L3 to S1
2. No urgent indication for surgical treatment according to the guidelines of DGNC and DGOOC
3. MRI determined pathology at treatment level that correlates to primary symptoms

Population 1 and 2
1. Age between 18 and 65 years
2. Skeletally mature
3. Willing and able to understand the study and to provide informed consent to participate
4. Physically and mentally able to participate in the study, including study treatment and post-study treatment pain
5. Able to understand and to complete study-relevant questionnaires in German language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Cardiac pacemaker
2. Pregnancy
3. Any degenerative muscular or neurological condition that would interfere with
4. Evaluation of outcome measures including but not limited to Parkinson's disease, amytrophic lateral sclerosis, multiple sclerosis, muscular dystrophy and myelopathic diseases of different causes myelopathy
5. Unable or unwilling to comply therapeutic instructions or to comply the follow-up visits at the study site
6. Active or chronic infection, systemic or local, systemic disease including HIV, AIDS, Hepatitis, Syphilis
7. Unable to undergo MRI
8. Active malignancy defined as a history of any invasive malignancy, except nonmelanoma skin cancer, unless the patient has been treated with curative intent and there have been no clinical signs or symptoms of the malignancy for a minimum of 5 years
neoplasia as the source of symptoms
9. Diabetes mellitus
10. Paget’s disease, osteomalacia, osteoporosis or other metabolic bone disease
11. Skin disease that influences sensory nerve function
12. Polyneuropathy
13. Autoimmune disorder that impacts the musculoskeletal system (i.e. lupus, rheumatoid arthritis, ankylosing spondylitis)
14. Acute episode or major mental illness (psychosis, major affective disorder or schizophrenia) and usage of anti-depressive drugs
15. Physical symptoms without a diagnosable medical condition to account for the symptoms, which may indicate symptoms of psychological rather than physical origin
16. Recent or current history of substance abuse (alcohol, narcotics, recreational drugs)
17. Pursuing personal litigation related to spinal diseases
18. Prisoner or ward of the state

Radiological Exclusion Criteria
1. Previous or acute spondylodiscitis
2. Previous compression or burst fracture at the level(s) to be treated
3. Central canal stenosis causing radiculopathy or clinical myelopathy (by MRI)
4. A spinal tumor

Date of first enrolment
01/04/2017

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
Austria

Study participating centre
Medical University Hospital Innsbruck
Anichstrasse 35

Innsbruck
Austria
6020

Sponsor information

Organisation
Medical University of Innsbruck

ROR
https://ror.org/03pt86f80

Funder(s)

Funder type
University/education

Funder Name
Medical University of Innsbruck

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/11/2017		Yes	No