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Rehabilitation treatment in patients with back pain

Submission date
14/12/2018

Recruitment status
No longer recruiting

Registration date
30/01/2019

Overall study status
Completed

Last Edited
30/01/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
One of the most common causes of back pain disease is low back pain (LBP). Low back pain creates significant social and economic problems for many people. Approximately 60-80 % of people suffer from low back pain at least once in their life.. Our goal is to test how well works the rehabilitation in the treatment of these patients.

Who can participate
Adults with low back pain, who are patients of our Rehabilitation Institute.

What does the study involve
Our patients stay in our facility for 4-6 weeks. During these weeks they will get this treatment: all patients will receive at least five individual 30-minute rehabilitation exercise per week. They will also undergo twelve 30-minute group exercise sessions per week in a gymnasium and swimming pool. In addition patients will receive other therapies, i.e., electrotherapy, hydrotherapy, and massages.

Before and after the treatment we will measure some values using methods called posturography and plantography. All we need patients to do is to stay unsupported for 30 seconds. We will compare the results before and after treatment.

Patients will be also asked to label the level of the pain on the scale before and after the treatment.

What are the possible benefits and risks
Patients can benefit from this study by experiencing relief from the low back pain, body posture and stability improvement. Others may benefit in the future from the information we find in this study.

We don´t expect any direct risk to the patients.

Where is the study run from
Rehabilitation Institut Brandýs nad Orlicí, Czech republic.

When is the study starting and how long is it expected to run
01/01/2017 to 30/06/2018.

Who is funding the study
This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Who is the main contact
Jiri Duchacek, sekretariat@rehabilitacniustav.cz, +420 465 544 207

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3/2018

Study information

Scientific Title
Efficacy of Rehabilitation Exercise and Treatment of Patients with Chronic Low Back Pain measured by posturography and plantography before and after the treatment

Study objectives
Evaluation of efficacy of our special rehabilitation treatment (INFINITY Method) measured by posturography and plantography before and after the treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Rehabilitation Institute Brandys nad Orlici, 01/02/2017

Study design
Interventional, non-randomsied

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Chronic low back pain

Interventions
All patients were hospitalized in our Rehabilitation Institute for 4-6 weeks and underwent:
1. At least five individual 30-minute special rehabilitation sessions per week
2. Six 30-minute group exercise sessions per week in a gymnasium and swimming pool

The INFINITY method is a rehabilitation approach based on neurophysiology, biomechanics, and anatomy. This Process encourages adjustment of the postural control system of the body, which gradually improves balance and symmetrization of the whole body in space, thus creating a precondition for better quality and more efficient movement. The rehabilitation is aimed at stabilizing, strengthening, and stretching of the thoracic, back, and abdominal muscles, including deep stabilizing system (DSS) with connection to diaphragmatic breathing. At the same time, the INFINITY method® enables increased mobility and flexibility via relaxation, stretching, mobilization and release of soft tissues of the musculoskeletal system. This rehabilitation approach uses active and passive exercises with supportive therapies including breathing exercises.

There was no participant follow-up.

Intervention Type
Other

Primary outcome measure
Objective posturography will be measured using the following parameters at at the baseline and after 4 weeks of treatment:
1. Feet parallel, eyes open (cm)- area before 2.76, area after 2.23
2. Feet parallel, eyes closed (cm)- area before 3.09, area after 2.40

Secondary outcome measures
Subjective pain reduction will be measured using the visual analogue scale (VAS) at baseline and after 4 weeks of treatment.

Overall study start date
01/01/2017

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Clinical diagnosis of low back pain
2. Confirmation of degenerative disease of lumbar spine by the MRI
3. The ability to stay unsupported for 30 seconds

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
331

Key exclusion criteria
1. Immobile patients

Date of first enrolment
30/06/2017

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
Czech Republic

Study participating centre
Rehabilitation Institut Brandys nad Orlici
Lazenska 58
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Sponsor information

Organisation
Rehabilitation Institut Brandys nad Orlici

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Sponsor type
Hospital/treatment centre

Website
https://www.rehabilitacniustav.cz/cs

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Rehabilitation Institut Brandys nad Orlici

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date