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A study to investigate the effectiveness of mechanical traction in treating people with lower back pain and sciatica caused by a herniated lumbar disc

Submission date
04/05/2018

Recruitment status
No longer recruiting

Registration date
26/06/2018

Overall study status
Completed

Last Edited
30/01/2020

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
Low back pain is a major health problem that is thought to be experienced by 60-90% of all people at some time during their life. Lumbar intervertebral disc disorder and herniated disc are medical terms used to describe a slipped or bulging disc, which is one of the most common back problems. A slipped disc may cause pressure on a nerve that can result in pain down one or both legs which is called sciatica. Treatments for a herniated disc include physiotherapy and spinal surgery to relieve pressure on the nerve. A treatment called traction has been used to treat back pain for almost 50 years but is no longer generally recommended. However, some recent research has shown that traction can be beneficial if used to treat back pain caused by a herniated disc rather than back pain from other causes. Previous studies have also shown that movement of the sciatic nerve can be limited in people with sciatica compared with people with no leg pain. The aims of this study are to see whether traction can help to improve movement of this nerve in people with a herniated disc, and to find out if traction can reduce pain in people with a herniated lumbar disc as well as possibly reduce the need for surgery.

Who can participate?
Patients aged 18 to 60 with a herniated lumbar disc

What does the study involve?
Participants are randomly allocated to either receive traction, continue with their pre-existing treatment, or receive traction with nerve mobilisation exercises. All participants are assessed by a Chartered Physiotherapist and if they are in a traction group they receive 8 traction treatment sessions over 4 weeks. After 4 weeks of traction or continuing with their pre-existing treatment all of the patients are reassessed. One of the assessments measures the movement of the sciatic nerve behind the knee using an ultrasound machine.

What are the possible benefits and risks of participating?
There may be immediate benefit for individuals who take part in this study in terms of pain

reduction and improved mobility. The results will provide a foundation for future research and inform clinical trials into the management of herniated disc and associated leg pain. There is no known risk associated with any of the processes in this study beyond possible short-term mild discomfort. The assessment of back movement and ultrasound scanning are non-invasive techniques. They do not involve any radiation and there are no known harmful effects. All movements will be performed within a range that does not cause any discomfort. However, any part of the testing will be stopped if participants feel any discomfort or do not want to continue for any other reason.

Where is the study run from?
Plymouth Marjon University (UK)

When is the study starting and how long is it expected to run for?
October 2017 to March 2020 (updated 09/09/2019, previously: February 2020)

Who is funding the study?
Plymouth Marjon University (UK)

Who is the main contact?
Mrs Sally Cinnamond

Contact information

Type(s)
Scientific

Contact name
Mrs Sally Cinnamond

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Additional identifiers

Protocol serial number
EP046

Study information

Scientific Title
The effects of pre-operative mechanical traction for patients with a confirmed diagnosis of disc herniation awaiting discectomy on pain and sciatic nerve biomechanics

Study objectives

This study aims to add to the body of evidence regarding traction as a treatment for disc herniation. In particular the study aims to determine any differences in outcome between traction treatment with and without an ultrasound guided nerve mobilisation technique performed during traction, which has not been previously identified in the literature. In addition, the effects of traction on the mechanics of the sciatic nerve are not known. Consequently, this study will investigate sciatic nerve movement via ultrasound before, during and after traction in patients with previously diagnosed lumbar disc pathology who are awaiting discectomy surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Plymouth Marjon University Research Ethics Panel, 18/01/2018, ref: EP046

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
All patients will be randomly placed in a group to receive traction or continue with their pre-existing treatment. All patients will be assessed by a Chartered Physiotherapist and if they are in a traction group they will receive 8 traction treatment sessions over 4 weeks. After 4 weeks of traction or continuing with their pre-existing treatment all the patients will be reassessed. One of the assessments will measure the movement of the sciatic nerve behind the knee using an ultrasound machine. The trialists want to see if traction can help to improve movement of this nerve in people with a herniated disc. They also want to find out if traction can reduce pain in people with a herniated lumbar disc as well as possibly reduce the need for surgery.

Updated 12/12/2018:
The trialists have conducted a pilot and have added a second treatment group to the study. This second treatment group will consist of 8 sessions of traction (as in treatment group 1) with the addition of nerve mobilisation exercises during the traction treatment.

Intervention Type
Other

Primary outcome(s)
Pain rating on a Numerical Pain Score. Participants will be asked to rate their severity of leg pain using a simple numerical Pain Score (Jensen et al.,1996), with a minimal clinically important difference (MICD) of 2.0 (Dworkin et al., 2005), measured at baseline, end of trial (1 month), and 6 months

Key secondary outcome(s))

1. The improvement will be measured with the Global Rating of Change Scale before and after the intervention (Dworkin et al., 2005) with a 15 point scale (-7 to +7), with a clinically important improvement defined as 5 or more (Stratford et al., 1994), measured at end of trial (1 month) and 6 months
2. Functional ability will be measured using the Oswestry Disability Index questionnaire; a valid and reliable disease-specific patient completed questionnaire of function (Fairbank and Pynsent, 2000), with a minimum clinically important difference of 12.8 (Copay et al., 2008), measured at baseline, end of trial (1 month), and 6 months
3. Medication: Type and dosage of medication that each participant is currently taking will be recorded and retrieved from patients' record by the research physiotherapist, measured at baseline, end of trial (1 month), and 6 months
4. Clinical examinations: Routine clinical tests including range of motion tests, straight leg raise test, neurological tests including reflex, ankle clonus, Babinski, dermatomes, and myotomes test will be included and carried out by the blinded research physiotherapist before and post intervention. A standardized passive straight leg raise test will be performed and the maximum angle between the straight leg and the longitudinal axis of the trunk will be measured using an inclinometer. Straight leg raise sign will be considered to be positive if the lift angle is less than 66°, with unilateral symptoms reproduced in the tested leg (Rebain et al., 2002, Tafazzoli and Lamontagne, 1996). Measured at baseline, end of trial (1 month), and 6 months
5. Sciatic/tibial nerve movement and spine and hip kinematics: Ultrasound recording (linear arrays centre frequency 7.5Mhz) during forward, backward and sideways bending will be taken at popliteal fossa of the knee in order to track the movement of the tibial nerve (Shum et al., 2013, Shum et al., 2015). This novel technique of measuring the movement of the tibial nerve has been demonstrated to have an excellent test-retest repeatability (ICC=0.97) (Shum et al., 2013). Measured at baseline, end of trial (1 month), and 6 months
6. Concurrent lumbar spine and hip movement will be measured using the three-dimensional inertia measurement unit (ProMove 3D, Inertia Technology, The Netherlands) which has been shown to be reliable and valid (Marin-Perianu et al., 2013). These markers will be placed on L1 spinous processes, sacrum and posterior thighs. Signals will be synchronised with the ultrasound readings and stored for offline analysis as in previous studies (Shum et al., 2013, Shum et al., 2015). These will help to identify the nerve movement when participants bend forward. Measured at baseline, end of trial (1 month), and 6 months
7. The level of psychological stress will be measured by the Distress and Risk Assessment Method (Hobby et al., 2001, Main et al., 1992, Trief et al., 2000) (Appendix IV), which is a combination of a modification of the Zung depression scale and the Modified Somatic Perception Questionnaire (MSPQ) to assess depression and somatisation of anxiety. Any patients that are identified as at risk will be excluded and referred to their GP as psychological interventions may be indicated with the following suggested cut-offs (Main et al., 1992)
• Normal modified Zung < 17
• At risk modified Zung 17 – 33 and MSPQ < 12
• Distressed Depressive modified Zung > 33
• Distressed Somatic MSPQ modified Zung 17 – 33 and MSPQ > 12
Measured at baseline

Completion date

01/06/2020

Eligibility

Key inclusion criteria

1. Patients aged between 18 and 60 years (both inclusive)
2. Diagnosis of a single level unilateral lumbar disc protrusion causing the appropriate nerve root impingement (within 6 months of diagnosis)
3. Decision to operate has been made and patient awaiting surgery
4. Patients who have residual leg pain as defined by a positive straight leg raise (SLR) sign (specified as less than 66° movement of the straight leg relative to the longitudinal axis of the trunk that the test reproduced unilateral symptoms in the tested leg)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Presence of the following red flag features – bladder/bowel dysfunction, history of cancer, thoracic night pain, previous history of lumbar surgery, saddle anaesthesia
2. Significant cardio-respiratory disorder
3. Pregnancy
4. Weight more than 20% of ideal norms for height and age or more than 140 kg

Date of first enrolment
01/06/2018

Date of final enrolment
01/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Plymouth Marjon University
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Sponsor information

Organisation
Plymouth Marjon University

ROR
https://ror.org/03f914y84

Funder(s)

Funder type
University/education

Funder Name
Plymouth Marjon University

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Sally Cinnamond (cinnamond.s@pgr.marjon.ac.uk). Anonymised, numerical data in excel format will be published on the University website. Consent for anonymised data sharing has already been specified in the subject information sheet and consent form.

IPD sharing plan summary
Available on request