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Dry needling of ligaments in the treatment of low back pain

Submission date
12/12/2022

Recruitment status
No longer recruiting

Registration date
22/12/2022

Overall study status
Completed

Last Edited
22/12/2022

Condition category
Musculoskeletal Diseases

[X] 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 (LBP) is one of the most common disabling health conditions worldwide. LBP is a disease resulting from the development of modern society. Evolution, as a result of which a person has adopted a vertical position of the body and the spread of a sedentary lifestyle contributes to the formation of balance disorders - both static and dynamic, and the occurrence of low back pain. This is an increasingly common problem that leads to a decrease in the quality of life, often disrupting the proper functioning of the whole organism, which affects large restrictions in professional and social life.
Dry needling is an alternative medicine technique similar to acupuncture.
The objective of this study is to assess the effectiveness of dry needling therapy and to compare real procedures to sham procedures in the treatment of low back pain. The primary study endpoints will be an analysis of pain relief change and functional improvement in two groups of patients (within and intergroup comparison before and after therapy). The secondary endpoints will be a follow-up observation (1 and 3 months after the end of the study - within and intergroup comparisons).

Who can participate?
Patients aged 18 years or above, both males and females, with chronic low back pain.

What does the study involve?
Participants will be randomised to receive dry needling or placebo therapy for 60 minutes, 2 times a week, 8 times in total. Measurements will be taken before and after therapy and during follow-up visits 1 and 3 months after the end of the study.

What are the possible benefits and risks of participating?
Benefits: Participants will receive a complete dry needling therapy, which may lead to reducing pain and functional improvement.
Risks: Temporary pain is expected up to 24 hours after each procedure (60-70% of treatments). Also, small bleeding or bruising may occur (15-20% cases and is considered normal). Drowsiness, tiredness or dizziness may appear in up to 3% of patients.

Where is the study run from?
Institute of Health Sciences, University of Opole, Poland

When is the study starting and how long is it expected to run for?
May 2020 to July 2024

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
KB/260/FI/2020

Study information

Scientific Title
Comparison of effectiveness of dry needling therapy performed on low back and pelvic ligaments on clinical effects and gait analysis in the treatment of low back pain - short and long term results

Study objectives
1. Dry Needling Therapy (DN) is effective in pain relief in patients with low back pain
2. DN is efficient in functional improvement in patients with low back pain
3. DN improves postural control in patients with low back pain
4. DN improves gait parameters in patients with low back pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/05/2020, The Research Ethics Committee from the Public Higher Medical Professional School in Opole (68 Katowicka St, 45-060 Opole, Poland; +48 601 444 943; no email provided), ref: KB/260/FI/2020

Primary study design
Interventional

Study design
Single-blind one centre randomized clinical interventional study with follow-up

Study type(s)
Treatment

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

Interventions
Patients from group A will receive a DN therapy that includes needles application within low back and pelvic ligaments.

Patients from group B will receive a sham therapy with usage of specialistic placebo needles, which telescopic construction allows placing needles on the skin without piercing it.

Single DN application will last 60 minutes. Each patient from two groups will have 8 sessions (twice a week) within 4 weeks. The intervention will occur in the clinician's office and be administered by certified physiotherapist and naturopathic practitioner. In addition, all patients will be supplemented with physical exercises performed throughout the therapy period. A single exercise series will last 45 minutes daily and will be carried out five times a week (Monday to Friday). Stabilization training will include:
- Techniques for the relaxation of the myofascial system on erector spinae muscle;
- Techniques for activating the neutral position of the lumbo-pelvic-hip complex and deep muscles;
- Stimulation of proper breathing and correct activation of the transverse abdominal muscle;
- Coordination of superficial and deep muscles activation;
- Postural and dynamic training.
The physical exercises will occur "one-on-one" method in the gym part of clinician's office and be administered by a certified athletic therapist. The training will be with the participants' intensity of 65-75% maximal heart rate (to monitor the application of exercises and the participants' status; the therapist observation diary will be kept).

Participants will be randomized with equal probability to real or placebo group using a central computer-generated random allocation. Subjects will be randomised in order of entry into the study. The group allocation will be independent of the time and person delivering the treatment.

Intervention Type
Other

Primary outcome(s)
Pain assessed with the Visual-Analogue Scale (VAS) and the Laitinen Pain Indicator Questionnaire before (baseline) and after therapy (week 4).

Key secondary outcome(s)
Before (baseline) and after therapy (week 4) and also 1 and 3 months after the end of study:
1. Quality of life assessed with the Roland–Morris Disability Questionnaire (RMDQ)
2. Posturography used to analyze the position of posture with open and closed eyes
3. Medical treadmill used to analyze gait
4. The Lasèque test used to measure the mobility range in the hip joint on the side of the herniated disc in the course of spinal discopathy. The starting position is lying down on the back with both legs straight. The examiner then slowly lifts one of the patient's legs while the knee is straight at the joint until pain occurs. The mobility range is measured in angle degrees using a goniometer
5. The Schober test used for evaluation of mobility of the lumbosacral spine. While the patient is in a standing position, the examiner marks 2 points on the patient's skin: at 10 cm above the line connecting the posterior superior iliac spines, and then at 5 cm below that line. The patient then slowly bends down as far as possible, while keeping the knees straight. The measurement is made using a tape measure. The obtained result is recorded with an accuracy of up to 0.5 cm
6. Pain assessed with the Visual-Analogue Scale (VAS) and the Laitinen Pain Indicator Questionnaire

Completion date
01/06/2024

Eligibility

Key inclusion criteria
1. Lumbosacral discopathy and chronic pain syndrome with pseudo-radicular radiation without neurological impairment
2. Never had any prior spinal surgical intervention
3. Diagnosis of LBP based on MRI scans, which clearly show the advancement of degenerative changes at the L5-S1 spine segment (the inclusion criterion was at least the 3rd grade in the Modic classification)
4. Aged 18 years or above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Acute and subacute spine pain episodes (up to 6 months)
2. Radicular pain syndrome
3. Degenerative changes on other segments of the spine (only initial, uncomplicated radiological changes (i.e., the 1st or the 2nd grade were allowed according to the Modic classification)
4. Past fractures within the spine
5. Tumors and hyperplastic changes
6. Spondylolisthesis
7. Rheumatic diseases
8. Cauda equina syndrome
9. Pregnancy in case of women
10. Chronic heart failure and peripheral vascular disease
11. Arrhythmia and implanted pacemaker
12. Implanted metal implants
13. Skin diseases in the area of shock wave treatment
14. Superficial or deep sensory impairment
15. Mental disorders and addictions
16. Cancer
17. Psoriasis and other immunological diseases
18. Infections
19. Antibiotics and any analgesic, anti-inflammatory, or antithrombotic agent
20. Damage of the vestibular system
21. Inflammation of the vestibular neuron or vestibulocochlear nerve disorder
22. Meniere's disease
23. Dysfunction of the inner ear
24. Other diseases of the cerebellum, spinal cord, and brainstem
25. Fear of needles

Date of first enrolment
01/02/2023

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
Poland

Study participating centre
University of Opole, Institute of Health Sciences
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Sponsor information

Organisation
University of Opole

Funder(s)

Funder type
University/education

Funder Name
Uniwersytet Opolski

Alternative Name(s)
University of Opole, Opole University, UO

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Single data for participants will be available from the date of first measurement up to 2 years after the end of the study. General statistical analysis will be available for institutions and journals from the end of the study for next 2 years. Specified data will be available upon request sent by e-mail to: katarzyna.rajfur@uni.opole.pl

IPD sharing plan summary
Available on request