

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Clinical effect and postural stability analysis of Extracorporeal Shock Wave Therapy (ESWT) in the treatment of Low Back Pain (LBP): randomized controlled trial

Protocol summary

Study aim

The objective of this study is to assess the effectiveness of Extracorporeal Shock Wave Therapy (ESWT) and to compare verum to sham procedure in the treatment of low back pain.

Design

Single blind prospective clinical study

Settings and conduct

Patients without ESWT (with sham probe) will receive: - shocks 2000 impulses -dose 0 mJ/mm² -frequency 5 Hz
The probe will generate a sound signal, but the treatment parameters will be zeroed and the device will be turned off with a display system in "standby mode"

Participants/Inclusion and exclusion criteria

Participants with lumbosacral discopathy and chronic pain syndrome with pseudo-radicular radiation without neurological impairment that have never had any prior spinal surgical intervention will be included in the study. The main exclusion criteria will be other musculoskeletal and neurological disorders, cancer and cardiopulmonary complications.

Intervention groups

Patients from group A will receive a focused shockwave therapy utilising the radial type pneumatic device without anaesthesia. The low back area will receive a total of 2000 shocks during a session (5 Hz; 0.1 mJ/mm²; 2.5 bars) and standard physical exercises. In group B there will be only a standard physical training (the same as in group A).

Main outcome variables

Subjective pain assessment, functional efficiency, and their degree of disability, postural stability: (1) the Visual-Analogue Scale (VAS), (2) the Laitinen Questionnaire Indicators of Pain (LQIP), (3) the Oswestry Disability Index (ODI), (4) the Roland-Morris Disability Questionnaire (RMDQ), (5) Lasegue's Test (LT), (6) Schober's Test (ST), (7) double-plate stabilometric

platform compatible with a computer-aided posturographic system model CQ Stab 2P

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131001014844N1**

Registration date: **2018-03-12, 1396/12/21**

Registration timing: **prospective**

Last update: **2018-03-12, 1396/12/21**

Update count: **0**

Registration date

2018-03-12, 1396/12/21

Registrant information

Name

Jakub Taradaj

Name of organization / entity

Academy School of Physical Education in Katowice

Country

Poland

Phone

0048668613945

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2639-06-09, 2018/03/19

Expected recruitment end date

2639-11-20, 2018/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical effect and postural stability analysis of Extracorporeal Shock Wave Therapy (ESWT) in the treatment of Low Back Pain (LBP): randomized controlled trial

Public title

ESWT in LBP: clinical effect and postural stability

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

lumbosacral discopathy: the diagnosis of LBP will be based on MRI scans, which allow to 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). chronic pain syndrome with pseudo-radicular radiation without neurological impairment that have never had any prior spinal surgical intervention

Exclusion criteria:

acute and subacute spine pain episodes (up to 6 months) radicular pain syndrome 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) past fractures within the spine tumors and hyperplastic changes spondylolisthesis rheumatic diseases cauda equina syndrome arrhythmia and implanted pacemaker pregnancy in case of women chronic heart failure and peripheral vascular disease implanted metal implants skin diseases in the area of ESWT treatment superficial or deep sensory impairment mental disorders and addictions cancer psoriasis and other immunological diseases antibiotics and any analgesic, anti-inflammatory, or antithrombotic agent, damage of the vestibular system inflammation of the vestibular neuron or vestibulocochlear nerve disorder Meniere's disease dysfunction of the inner ear, and other diseases of the cerebellum, spinal cord, and brainstem

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomisation using computer and envelopes

Blinding (investigator's opinion)

Single blinded

Blinding description

The participant will be blinded in the present study, where the probe will generate a sound signal, but the treatment parameters will be zeroed and the device will be turned off with a display system in "standby mode"

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Research Ethics Committee from the Wroclaw Medical University

Street address

1 Pasteur St

City

Wroclaw

Postal code

50-361

Approval date

2638-04-26, 2017/02/06

Ethics committee reference number

KB-75/2017

Health conditions studied**1****Description of health condition studied**

low back pain

ICD-10 code

M54.5

ICD-10 code description

M00-M99 Diseases of the musculoskeletal system and connective tissue

Primary outcomes**1****Description**

The primary outcome will be an analysis of pain relief change and functional improvement in two groups of patients (within and intergroup comparisons)

Timepoint

before and after therapy

Method of measurement

(1) the Visual-Analogue Scale (VAS), (2) the Laitinen Questionnaire Indicators of Pain (LQIP), (3) the Oswestry Disability Index (ODI), (4) the Roland-Morris Disability Questionnaire (RMDQ), (5) Lasegue's Test (LT), (6) Schober's Test (ST), (7) double-plate stabilometric

platform compatible with a computer-aided posturographic system model CQ Stab 2P

Secondary outcomes

1

Description

The secondary outcome will be a follow-up observation (within and intergroup comparisons).

Timepoint

1 and 3 months after the end of the study

Method of measurement

(1) the Visual-Analogue Scale (VAS), (2) the Laitinen Questionnaire Indicators of Pain (LQIP), (3) the Oswestry Disability Index (ODI), (4) the Roland-Morris Disability Questionnaire (RMDQ), (5) Lasegue's Test (LT), (6) Schober's Test (ST), (7) double-plate stabilometric platform compatible with a computer-aided posturographic system model CQ Stab 2P

Intervention groups

1

Description

Intervention group: Patients from this group will receive a focused shockwave therapy utilising the radial type pneumatic device without anaesthesia. The low back area will receive a total of 2000 shocks during a session (5 Hz; 0.1 mJ/mm²; 2.5 bars). Each patient will have 10 sessions (twice a week) within 5 weeks. In addition, all patients will be supplemented with physical exercises performed throughout the therapy period. A single 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.

Category

Treatment - Devices

2

Description

Control group: Patients from this group will receive a sham therapy (the probe will generate a sound signal, but the treatment parameters will be zeroed and the device will be turned off with a display system in "standby mode"). In addition, all patients will be supplemented with physical exercises (the same as in intervention group)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Public Higher Medical Professional School

Full name of responsible person

Jakub Taradaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Public Higher Medical Professional School

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Public Higher Medical Professional School
Full name of responsible person
Karolina Walewicz
Position
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

We are going to prepare a study website (when it will be registered) and enclose these documents

When the data will become available and for how long

When the first participant will be recruited and to the moment publishing results (when the articles will appear on WoS and PubMed)

To whom data/document is available

People, who will receive a password from the web moderator (registration process)

Under which criteria data/document could be used

Analysed research data for registered persons

From where data/document is obtainable

We will prepare a research website (to this date please use email addresses j.taradaj@awf.katowice.pl or karolina.w101@wp.pl)

What processes are involved for a request to access data/document

Standard registration process to receive login and password

Comments