Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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

Email address

j.taradaj@awf.katowice.pl

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 pacemake 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
Street address
68 Katowicka St
City
Opole
Postal code
45-060
Phone
+48 77 441 08 82
Email
j.taradaj@awf.katowice.pl

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Public Higher Medical Professional School
Full name of responsible person
Tomasz Halski
Street address
68 Katowicka St
City
Opole
Postal code
45-060
Phone
+48 77 442 35 17
Email
tomhalski@wp.pl
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
Adjunct
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
68 Katowicka St
City
Opole
Province
Silesia
Postal code
45-060
Phone
+48 77 442 35 50
Email
karolina.w101@wp.pl

Person responsible for scientific inquiries

Contact
Name of organization / entity
Public Higher Medical Professional School
Full name of responsible person
Karolina Walewicz
Position
Adjunct
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
68 Katowicka St
City
Opole
Province
Silesia
Postal code
45-060
Phone
+48 77 442 35 50
Email
karolina.w101@wp.pl

Person responsible for updating data

Contact
Name of organization / entity
Public Higher Medical Professional School
Full name of responsible person
Jakub Taradaj
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
68 Katowicka St
City
Opole
Province
Silesia
Postal code
45-060
Phone
+48 77 441 08 82
Email
j.taradaj@awf.katowice.pl

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