

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of the Effect of Classical Physical Therapy Agents and Extracorporeal Shock Wave Therapy (ESWT) on Pain, Disability, Functional Status and Depression in Patients with Chronic Low Back Pain; Prospective randomized controlled trial

Protocol summary

Study aim

The aim of this study is to compare the effectiveness of classical physical therapy agents and extracorporeal shock wave therapy (ESWT) on pain, disability, functional status and depression in patients with chronic low back pain.

Design

Two arm parallel group randomised trial

Settings and conduct

It was decided to study with 80 patients with G-power program. Patients will be divided into two groups randomly. Randomization will be done with closed envelope. Evaluations will be repeated before treatment, after treatment and at 3rd month.

Participants/Inclusion and exclusion criteria

Participants/Inclusion criteria :Patients with low back pain who have been diagnosed with chronic low back pain for at least 3 months between 18- 65 years old. Exclusion criteria: Operational history of lumbar spine region. Vertebral compression fracture. Spinal tumors. Intervertebral disc infections. Inflammatory rheumatic disease. Pregnant patients. Heart disease. Structural abnormalities. Whether the patient is unwilling or unable to participate for any reason. Deciding whether the clinician does not benefit the patient.

Intervention groups

For Group 1, classic physical therapy agents (Transcutaneous Electrical Nerve Stimulation 20 minutes, hot pack 20 min, ultrasound 5 min) to be applied. Group 2 will be applied at least 2 days apart and 5 sessions will be done in 2-3 weeks. The shock wave probe will be applied vertically to the quadratus lumborum, sacroiliac joint and the patient's pain after application of the joining gel, and the 20mm applicator will be applied at 2600 shots at a pressure of 2.8 bar and at a frequency of 10 Hz eswt.

Main outcome variables

The Beck Depression Scale will be used to determine the levels of depression, and Oswestry, Health Assessment Questionnaire (Haq). Visual analogue scale (VAS) and Algometer will be used to question the pain status in individuals.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190411043240N1**

Registration date: **2019-05-23, 1398/03/02**

Registration timing: **prospective**

Last update: **2019-05-23, 1398/03/02**

Update count: **0**

Registration date

2019-05-23, 1398/03/02

Registrant information

Name

mehmet okcu

Name of organization / entity

Ahi evran university

Country

Turkey

Phone

+90 386 441 02 44

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-20, 1398/04/29

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Classical Physical Therapy Agents and Extracorporeal Shock Wave Therapy (ESWT) on Pain, Disability, Functional Status and Depression in Patients with Chronic Low Back Pain; Prospective randomized controlled trial

Public title

Effect of the Extracorporeal Shock Wave Therapy (ESWT) in Chronic Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male and female patients with low back pain who have been diagnosed with chronic low back pain for at least 3 months between 18- 65 years old Patients who are able to understand correctly the patient information form and cooperate Patients consenting to participate in the study according to the informed consent form

Exclusion criteria:

Operational history of lumbar spine region. Vertebral compression fracture Spinal tumors Intervertebral disc infections Inflammatory rheumatic disease Pregnant patients Heart disease Structural abnormalities Whether the patient is unwilling or unable to participate for any reason Deciding whether the clinician does not benefit the patient

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

simple, individual, sealed envelopes

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kirsehir Ahi Evran University
Faculty of Medicine

Street address

Ahi Evran Üniversitesi Tıp Fakültesi Bağbaşı Yerleşkesi
Merkez / Kirsehir/Turkey

City

Kirsehir

Postal code

40100

Approval date

2018-11-13, 1397/08/22

Ethics committee reference number

2018-21/173

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

chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

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

The Beck Depression Scale will be used to determine the levels of depression, and Oswestry, Health Assessment Questionnaire (Haq). Visual analogue scale (VAS) and Algometer will be used to question the pain status in individuals.

Timepoint

before treatment, after treatment and at 3rd month.

Method of measurement

The Beck Depression Scale will be used to determine the levels of depression, and Oswestry, Health Assessment Questionnaire (Haq). Visual analogue scale (VAS) and Algometer will be used to question the pain status in individuals.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: extracorporeal shock wave therapy. The model name of the device is Modus ESWT. Device has CE ("Conformité Européene") mark. The global product (barcode) number is 8680050920224. The device is registered in Turkey Pharmaceuticals and Medical Devices National Data Bank (TİTUBB). Extracorporeal shock wave therapy (ESWT) is a noninvasive procedure using single-pulse acoustic waves produced outside the body and focused on a specific area in the body. Studies have shown that ESWT is an effective and long-term pain-reducing method for soft tissue diseases such as plantar fasciitis and achilles tendinopathy; ESWT is routinely applied in achilles tendinopathy and plantar fasciitis. Shock waves promote axonal regeneration of peripheral nerves by various molecular reactions. ESWT has been reported to induce analgesia by biochemical changes in the nerve fiber itself and to reduce inflammation of soft tissues. It has also been shown that ESWT promotes revascularization, stimulates or re-activates the healing process of connective tissues, including tendons and bones, thereby alleviating pain and improving function. ESWT can be used to relieve pain as well as to improve muscle strength through proper motor stimulation by shock waves of muscles and tendons. ESWT device user's manual also includes low back pain in the ESWT indication list, but ESWT; There are few studies on the effects of low back pain on pain, disability and depression. ESWT will be applied in a total of 5 sessions 2-3 weeks after a minimum of 2 days. After the application of the joining gel, the shock wave probe will be placed perpendicular to the areas of the Quadratus Lumborum, Sacroiliac joint and the patient's pain, and the 20mm applicator will be applied at a pressure of 2.8 bar and at a frequency of 10 Hz with 2600 shots.

Category

Treatment - Devices

2

Description

Intervention group: Classical Physical Therapy Agents. Classic physical therapy agents TENS 20 minutes, Hot pack 20 min, ultrasound 5 min to be applied for 15 days.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kirsehir hospital

Full name of responsible person

Mehmet Okcu

Street address

No:1, Kervansaray Mahallesi, 2019. Sokak, Kirsehir, Turkey

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Kirsehir Ahi Evran

Full name of responsible person

Mehmet Okcu

Street address

No:1, Kervansaray Mahallesi, 2019. Sokak, Kirsehir, Turkey City Kirsehir

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iletisim@ahievran.edu.tr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The University of Kirsehir Ahi Evran

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

Ahi evran university

Full name of responsible person

Mehmet Okcu

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Comparison of the Effect of Classical Physical Therapy Agents and Extracorporeal Shock Wave Therapy (ESWT) on Pain, Disability, Functional Status and Depression in Patients with Chronic Low Back Pain; Prospective randomized controlled trial

When the data will become available and for how long

When the study starts, study will become available and it will ends after 1 year after the end of study

To whom data/document is available

For medical doctors, physiotherapists

Under which criteria data/document could be used

Data/documents could be used after taking permission

From where data/document is obtainable

From researcher

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

People which want to access data/document can write via e-mail.

Comments