

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Development of a protocol for the prevention of back pain based on the use of electrical stimulation of the lumbar region.

Protocol summary

Study aim

Ultrasound examination of the effect of electrical stimulation of the lumbar region on the thickness of lumbar fascia in healthy people.

Design

This is a double-blind, randomized, Phase 2 clinical trial with 100 patients. The participants are randomly assigned to either the intervention group or the control group using the flip-the-coin method to ensure unbiased assignment

Settings and conduct

Before starting the intervention, participants will undergo assessments including an ultrasound examination (using the S9 ultrasound machine by SonoScape Corporation, China) to measure lumbar fascia thickness. Additionally, back arch angle and flexibility will be assessed using a flexible ruler, Spinal Mouse, and the sit & reach test. Following the assessments, participants will receive TENS current in the lower back for two weeks, consisting of ten sessions. After completing the sessions, a follow-up examination will be conducted. A two-week follow-up evaluation will also be performed to assess long-term effects. All stages of the study will take place at the Biomechanics Research Center - Department of Physical Medicine and Rehabilitation, AJA University of Medical Sciences.

Participants/Inclusion and exclusion criteria

The study will include healthy subjects with a BMI ranging from 18.5 to 30, who have not experienced any back pain in the past twelve months. Participants will be excluded if they have any musculoskeletal disorders or if they are using painkillers or anti-inflammatory drugs.

Intervention groups

The study involves two groups: the intervention group receiving electrical stimulation in the lumbar region, and the control group receiving a sham intervention with a device operating below the effective threshold.

Main outcome variables

lumbar fascia thickness; lumbar flexion angle; lumbar

arch angle; Lumbar flexibility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200423047173N2**

Registration date: **2023-06-16, 1402/03/26**

Registration timing: **prospective**

Last update: **2023-06-16, 1402/03/26**

Update count: **0**

Registration date

2023-06-16, 1402/03/26

Registrant information

Name

Hassan Tamartash

Name of organization / entity

Tarbiat Modares University

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development of a protocol for the prevention of back pain based on the use of electrical stimulation of the lumbar region.

Public title

Investigating the effect of electrical stimulation of the lower back in preventing back pain.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

No history of back pain in the last 12 months The minimum age to enter the study is 20 and the maximum is 50 years. BMI index between 18-30.5 for all participants in the study.

Exclusion criteria:

History of spine and lower limb surgery. The presence of postural disorders and major deformities in the spine such as scoliosis, kyphosis, etc. Suffering and history of rheumatic diseases, infectious diseases, cardiovascular disorders, fibromyalgia, osteoporosis. History of fracture in the spine or tumors of the spine and lower limbs. Disorders of vestibular, vision and mental system. Use of corticosteroid drugs and history of injections in the lower back area (oral administration or injection of steroids). Carrying out intense physical activity during the study period, inability to perform tests, or unwillingness to continue tests.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants, including individuals without back pain, were randomly divided into two groups using the coin flip technique. The first group received TENS current applied to the lower back, while the second group served as the control group and received sham TENS current. This protocol was conducted for a duration of two weeks, with each participant receiving ten sessions of TENS current in the lower back.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the current study, the clinical caregiver responsible for the patients and the individual conducting the clinical tests and interventions on the participants will be blinded

to the study objectives. Additionally, the data analysis before and after the interventions will be performed by an independent person who is unaware of the study conditions.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research ethics Committee of AJA University of Medical Sciences

Street address

Shahid Etemadzadeh Street, West Fatemi Street, Tehran, Iran

City

Tehran

Province

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Postal code

1411718541

Approval date

2023-05-15, 1402/02/25

Ethics committee reference number

IR.AJAUMS.REC.1402.037

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

Low back pain

ICD-10 code

M54.40

ICD-10 code description

Lumbago with sciatica, unspecified side

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

Changes in the thickness of the lumbar fascia

Timepoint

Before the start of the intervention, after the completion of the intervention sessions, two weeks after the end of the study.

Method of measurement

Ultrasound device

2

Description

Changes in the angle of the back arch

Timepoint

Before the start of the intervention, after the completion of the intervention sessions, two weeks after the end of the study.

Method of measurement

Spinal mouse

3

Description

Maximum back bending angle

Timepoint

Before the start of the intervention, after the completion of the intervention sessions, two weeks after the end of the study.

Method of measurement

Flexible Ruler

Secondary outcomes

1

Description

Checking the flexibility of the waist area

Timepoint

Before the start of the intervention, after the completion of the intervention sessions, two weeks after the end of the study.

Method of measurement

Sit & reach test

Intervention groups

1

Description

In the intervention group, participants will receive conventional TENS current with a frequency of 100 Hz, a pulse duration of 50 microseconds, and an intensity up to the tolerance threshold for a duration of 45 minutes.

Category

Prevention

2

Description

In the control group, participants will receive conventional TENS current with a frequency of 100 Hz, a pulse duration of 50 microseconds, and an intensity up to the tolerance threshold for a duration of 45 minutes. However, the intensity used in the control group will be significantly lower than the tolerance threshold.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Biomechanics Research Center - Department of Physical Medicine and Rehabilitation of AJA University

Full name of responsible person

Dr Sharif Najafi

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Shahid Etemadzadeh Street, West Fatemi Street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr Reza Mosaeed

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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

Artesh University of Medical Sciences

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

Artesh University of Medical Sciences

Full name of responsible person

Dr Hassan Tamartash

Position

Non-Academic Specialized Doctorate in Physiotherapy

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr Hassan Tamartash

Position

Physiotherapy Doctorate Non-Academic

Latest degree

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Other areas of specialty/work

Physiotherapy

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data can be shared after de-identifying individuals to ensure privacy and confidentiality.

When the data will become available and for how long

The access period will commence 6 months after the publication of the results.

To whom data/document is available

The data will be exclusively accessible to researchers affiliated with academic and scientific institutions.

Under which criteria data/document could be used

Special analysis on the provided data is not permitted, and any actions related to data analysis must be coordinated with the authors of the study.

From where data/document is obtainable

By sending an email to: h.tamartash@modares.ac.ir

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

Once an email is sent to the specified address, explaining the reason for requesting access to the data,

the eligible applicants can expect to receive access to the data within a maximum of two weeks, following an

agreement with the authors of the study.
Comments