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

Country
Iran (Islamic Republic of)

Phone
+98 21 8288 3819

Email address
h.tamartash@modares.ac.ir

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 pastural 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
Tehran

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
Street address
Shahid Etemadzadeh Street, West Fatemi Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
Biomed@ajaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Dr Reza Mosaeed
Street address
Shahid Etemadzadeh Street, West Fatemi Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
Med@ajaums.ac.ir
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

Street address
Shahid Etemadzadeh Street, West Fatemi Street, Tehran, Iran

City
tehran

Province
Tehran

Postal code
1411718541

Phone
+98 21 8609 6350

Email
mojtaba.tamartash@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Artesh University of Medical Sciences

Full name of responsible person
Dr Hassan Tamartash

Position
Physiotherapy Doctorate Non-Academic

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Shahid Etemadzadeh Street, West Fatemi Street, Tehran, Iran

City
tehran

Province
Tehran

Postal code
1411718541

Phone
+98 21 4432 2852

Email
mojtaba.tamartash@gmail.com

Person responsible for updating data

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
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Other areas of specialty/work
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Street address
Shahid Etemadzadeh Street, West Fatemi Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1411718541

Phone
+98 21 8609 6350

Email
mojtaba.tamartash@gmail.com

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