Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of iliopsoas muscle dry needling technique on the clinical symptoms of subject with non-specific low back Pain

Protocol summary

Study aim

Investigate the effect of dry needling on the trigger points of the iliopsoas muscle in patients with non-specific chronic back pain.

Design

Clinical trial with control group, with parallel groups, Tow-blinded, randomized, without phase on 40 patients, randomization allocation software was used for randomization

Settings and conduct

Patients will be divided into two groups by the table of numbers. The first group will receive dry needling of the iliopsoas muscle during 6 sessions. At the same time, they will also benefit from conventional physiotherapy treatment, but the control group will only use conventional physiotherapy treatment. The location of the project will be at the Physiotherapy clinic of Asadabadi Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) People between 30 and 65 years old 2) Chronic back pain that lasts 3 months or more 3) People with a disability score of >40 in the QBPDS questionnaire) 4) Not receiving any other physiotherapy treatment while participating in the study. 5) The presence of a trigger point in the iliopsoas muscle

Intervention groups

The intervention group includes patients with non-specific chronic back pain, whose conventional physical therapy includes continuous ultrasound treatment with a frequency of 1 MHz and intensity of 1.5 for 6 minutes, TENS burst electric current with a frequency of 2 Hz and diversion of 100 µs for 20 minutes, and the use of hot packs at the same time. Apply with current. Exercises are taught in the clinic under the supervision of a physiotherapist. 6 sessions of dry needling treatment are also done for them. The control group includes patients with non-specific chronic back pain who only receive conventional physiotherapy.

Main outcome variables

Pain; intensity in trigger points of Iliopsoas muscles; Intensity of back pain; Pressure threshold of trigger point pain; Functional disability

General information

Reason for update

I want to change the expected start date of the patient intake to 2024-10-22 due to the university's inability to solve the problems encountered in order to prepare the tools needed to measure this plan, and subsequently change the expected end date of the patient intake to 2025-03-05.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200215046499N4**
Registration date: **2023-09-24, 1402/07/02**
Registration timing: **prospective**

Last update: **2024-09-07, 1403/06/17**
Update count: **1**

Registration date

2023-09-24, 1402/07/02

Registrant information

Name

Hakimeh Adigozali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2025-03-05, 1403/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of iliopsoas muscle dry needling technique on the clinical symptoms of subject with non-specific low back Pain

Public title

Effect of dry needling technique of iliopsoas muscle

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People between 30 and 65 years old Chronic back pain that lasts for 3 months or more People with a disability score of >40 in the QBPDS Questionnaire) Not receiving any other physiotherapy treatment while participating in the study The presence of a trigger point in the muscle Iliposoas

Exclusion criteria:

Patients with sensory and/or coagulation disorders History of spine surgery Heart complications Simultaneous severe disease of the central or peripheral nervous system, Epilepsy Needle phobia Serious pathologies Specific back pain (for example, the presence of spinal canal stenosis, spondylolisthesis, tumors, etc.) People who have contraindications for transcutaneous electrical stimulation (TENS) and (US) will be excluded

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by someone outside the research team with a 1:1 parallel allocation method, which uses a computer randomization program to assign participants to groups, using blocks of four and six. Then he uses opaque sealed envelopes and hides the allocation of groups with the method pre-labeled with the letters A and B.) They will be placed in two control and intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blind, participants: In the control group, patients are told that routine physical therapy is the only treatment. Outcome assessor: The person who assesses the patients does not know whether they belong to the control or intervention group Data analyst: The person who evaluates the data of the two groups does not know whether they belong to the contr

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of medical sciiences

Street address

Faculty of Rehabilitation sciences, Tabriz University of medical sciences,29 Bahman Blvd, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Approval date

2023-09-04, 1402/06/13

Ethics committee reference number

IR.TBZMED.REC.1402.424

Health conditions studied

1

Description of health condition studied

Non-specific low back Pain

ICD-10 code

M54.5

ICD-10 code description

low back pain

Primary outcomes

1

Description

Pain intensity of trigger points

Timepoint

Before and after intervention

Method of measurement

Algometer

Secondary outcomes

1

Description
Pain intensity of back
Timepoint
Before and after intervention
Method of measurement
Numeric pain rating scale (NPRS)

2

Description
Intensity of depression and anxiety
Timepoint
Before and after intervention
Method of measurement
Hospital Anxiety and Depression Scale(HADS)

3

Description
Intensity of functional disability
Timepoint
Before and after intervention
Method of measurement
Quebec back pain disability scale(QBPDS)

4

Description
Pain pressure threshold of trigger points
Timepoint
Before and after intervention
Method of measurement
Algometer

Intervention groups

1

Description
Intervention group: In addition to receiving dry needling during 6 sessions (with a sterile dong bang needle with a size of 30*50 mm), they are included in the conventional physiotherapy treatment provided by the physiotherapist. People in the intervention group of the conventional treatment (as a modality It is possible to use continuous ultrasound with a frequency of 1 MHz and an intensity of 1.5 for 6 minutes (same side of the waist), using a burst TENS electric current with a frequency of 2 Hz and a diversion of 100 µs for 20 minutes, and using a hot pack simultaneously with the current. Also, sports exercises designed in the clinic are taught to the person under the supervision of a physiotherapist
Category
Rehabilitation

2

Description
Control group: People in the control group received conventional treatment (as a modality, continuous ultrasound with a frequency of 1 MHz and intensity of 1.5 for 6 minutes (same side of the back), use of TENS burst electric current with a frequency of 2 Hz and diversion of 100 µs for 20 minutes and using The hot pack is applied simultaneously with the current (76).Also, the person is taught the designed sports exercises in the clinic under the supervision of the physiotherapist.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Asad Abadi hospital, physical therapy clinic
Full name of responsible person
Hakimeh Adigozali
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Asad-Abadi hospital, Bahar avenue, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
Street address
Central building, Tabriz university of medical sciences, university street, Tabriz
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Hakimeh adigozali
Position
assistant professor
Latest degree
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Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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