

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The Comparison of the Effectiveness of Electroacupuncture and Routine physiotherapy on Pain, Functional disability and Ultrasonographic changes of Gluteus Maximus in Non specific Chronic Low back Pain Patients with Gluteus Maximus Trigger Points

Protocol summary

Study aim

The effect of electroacupuncture on pain, functional disability and ultrasonographic changes of gluteus maximus muscle in patient with non specific chronic low back pain with gluteus maximus trigger point.

Design

The clinical trial with control group, parallel group with 40 patients, randomized

Settings and conduct

40 volunteers with non specific low back pain will be randomly assigned to two intervention group including routine treatment of physiotherapy and routine treatment with electroacupuncture

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients with non specific chronic low back pain at least three months from the onset of their pain and Gluteus Maximus muscle trigger points, Number of trigger points 2_4, Scale of visual analog scale of pain 1_4, Score of functional disability questionnaire 1_15 Exclusion criteria included fear of needle, hypersensitivity to needle, fibromyalgia, lumbar disk herniation, spinal cord stenosis, low back arthritis, pregnancy, taking anticoagulants and hip surgery

Intervention groups

In the intervention group, the electroacupuncture treatment will be performed for two sessions per week and each session is done for 20 minutes and treatment is done in 4 sessions. In the control group, subjects 10 sessions will be treated routine physiotherapy 3 times per week and the duration of treatment will be 45 minutes per session.

Main outcome variables

The size of gluteus maximus muscle, pain, functional disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150602022539N9**

Registration date: **2019-03-28, 1398/01/08**

Registration timing: **prospective**

Last update: **2019-03-28, 1398/01/08**

Update count: **0**

Registration date

2019-03-28, 1398/01/08

Registrant information

Name

Ziaeddin Safavi Farokhi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

Email address

zsafavi@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the Effectiveness of Electroacupuncture and Routine physiotherapy on Pain, Functional disability and Ultrasonographic changes of Gluteus Maximus in Non specific Chronic Low back Pain Patients with Gluteus Maximus Trigger Points

Public title

The Effect of Electroacupuncture in Non specific Low Back Pain Patients with Gluteus Maximus Trigger Points

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with non specific chronic low back pain at least three months from the onset of their pain Gluteus Maximus trigger points 2_4 trigger points Visual analogues scale of pain 1_4 Score of functional disability questionnaire 1_15

Exclusion criteria:

Diabetes Fear from needle Needle sensitivity Pregnancy Systemic, infectious and inflammatory disease of vertebral column Acute and sub acute low back pain Disc herniation Tumor Osteomyelitis Ankylosing spondylitis Vertebral fracture Scoliosis Taking anticoagulants Depression Fibromyalgia Spinal cord stenosis Hip joint surgery Osteoporosis

AgeFrom **20 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization method: Permuted block randomization Randomization unit: Person Stratified randomization: Not done Randomization instrument: Random allocation software (Excel) Random sequence generation: Used random blocks, each block containing 4 people and allocated a number from 1 to 6 to each block Allocation concealment: Because of physiotherapy interventions for patients, allocation concealment is not possible

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The clinical trial with control group, parallel group with 40 patients, randomized

Secondary Ids

empty

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

Ethic committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Kilometer 5 Damghan road, Semnan

City

Semnan

Province

Semnan

Postal code

5319899951

Approval date

2019-01-15, 1397/10/25

Ethics committee reference number

IR.SEMUMS.REC.1397.256

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

Non specific chronic low back pain with trigger point in gluteus Maximus muscle

ICD-10 code

M54.5

ICD-10 code description

Low back pain

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

The size of gluteus Maximus muscle

Timepoint

First session of treatment, The last session of treatment and Two weeks after the last meeting

Method of measurement

Ultrasonographic apparatus

2**Description**

Pain

Timepoint

First session of treatment, The last session of treatment and Two weeks after the last meeting

Method of measurement

Visual Analog Scale

3

Description

Functional disability

Timepoint

First session of treatment, The last session of treatment and Two weeks after the last meeting

Method of measurement

Oswestry disability index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, the electroacupuncture treatment was performed for two sessions per week and each session is done for 20 minutes and treatment is done in 4 sessions. The treatment method in all sessions is one way and it will be under the supervision of a therapist.

Category

Rehabilitation

2

Description

Control group: In the control group, the interventions will be done 10 sessions routine physiotherapy 3 times per week and the duration of treatment will be 45 minutes per session.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences

Full name of responsible person

Ziaeddin Safavi Farokhi

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Mashahir Square, in front of Helal Ahmar, Semnan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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Street address

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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

Vice chancellor for research, Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Ziaeddin Safavi Farokhi

Position

Ph.D, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Contact

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Full name of responsible person

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Position

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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

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