

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect of neuromuscular electrical stimulation for endometriosis associated pain

Protocol summary

Study aim

Effect of neuromuscular electrical stimulation for endometriosis associated pain

Design

Double Blinded Randomized Clinical Trial

Settings and conduct

Intervention group: patients in the treatment group received electrical stimulation by using the electrical stimulation device. It applied 2 gel pads attached on the S3 and S4 region with frequency of 85Hz and pulse duration 75ms for 30minutes each session, once daily, 3sessions weekly for a total of 10 sessions. Control group: Patients did not receive electrical stimulation using an electrical stimulation device.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: average age of 18-45 years, patients with endometriosis -associated pain documented endometriosis by MRI or sonography that were undergoing medication. Exclusion Criteria: Patients with pace maker, Patients who had electrical stimulation in last 1month, patient that having surgical plan in next 3 months or had surgery in last 6 months, uremia, uncontrolled thyroid dysfunction, active lumbosacral radiculopathy, peripheral neuropathy, collagen vascular disease, pregnancy, addiction to drug or alcohol.

Intervention groups

Intervention group: patients in the treatment group received electrical stimulation by using the electrical stimulation device. It applied 2 gel pads attached on the S3 and S4 region with frequency of 85Hz and pulse duration 75ms for 30minutes each session, once daily, 3sessions weekly for a total of 10 sessions. Control group: Patients did not receive electrical stimulation using an electrical stimulation device.

Main outcome variables

Pain, Quality of Life

General information

Reason for update

It was big mistake in trial onset. please correct this.

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N107**

Registration date: **2021-01-27, 1399/11/08**

Registration timing: **prospective**

Last update: **2021-02-01, 1399/11/13**

Update count: **1**

Registration date

2021-01-27, 1399/11/08

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-17, 1399/11/29

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of neuromuscular electrical stimulation for endometriosis associated pain

Public title

Effect of neuromuscular electrical stimulation for endometriosis associated pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Average age of 18-45 years Patients with endometriosis - associated pain Documented endometriosis by MRI or sonography

Exclusion criteria:

Patients with pace maker Patients who had electrical stimulation in last 1month Patient that having surgical plan in next 3 months or had surgery in last 6 months Uremia Uncontrolled thyroid dysfunction Active lumbosacral radiculopathy Peripheral neuropathy Collagen vascular disease Pregnant patients Patient with addiction to drug or alcohol

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed for the two intervention and control groups by using 4, 6 and 8 permutation blocks extracted from the site www.sealedenvelope.com.

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 Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz

University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2019-08-24, 1398/06/02

Ethics committee reference number

IR.SUMS.MED.REC.1398.361

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Pain

Timepoint

هر هفته پس از انجام تحریک الکتریکی

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Quality of Life

Timepoint

After Intervention

Method of measurement

Moorehead-Ardelt Quality of Life Questionnaire II

Intervention groups

1

Description

Intervention group: patients in the treatment group received electrical stimulation by using the electrical stimulation device. It applied 2 gel pads attached on the S3 and S4 region with frequency of 85Hz and pulse duration 75ms for 30minutes each session, once daily, 3sessions weekly for a total of 10 sessions.

Category

Treatment - Other

2

Description

Control group: Patients did not receive electrical stimulation using an electrical stimulation device.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zynab Hospital

Full name of responsible person

Noshin Abbasi

Street address

Zynab Hospital, Defa moghadas junction

City

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Postal code

7134844119

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Email

zeinabhp@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaienzadeh

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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vcrd@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Abbasi

Position

Gynecology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Gynecology Department, Faghihi Hospital, Zand Street

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jahromi153@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zohreh Tavana

Position

Gynecologist

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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zotavana27@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

5th floor, Mohammad Rasoul Allah Research Tower,
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masihifarzaneh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against our polices.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available