

# 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](http://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**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3726 6811

**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 Rezaiezenzadeh

**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

**City**

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**Province**

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**Email**

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

**Street address**

Gynecology Department, Faghihi Hospital, Zand Street

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## 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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**Postal code**

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**Phone**

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**Email**

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