

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Evaluation the effect of acupuncture on pain of patients with trigeminal neuralgia

#### Protocol summary

##### Study aim

The aim of this study is evaluating the efficacy of a non-pharmacological treatment "acupuncture" for treating refractory trigeminal neuralgia

##### Design

In this clinical trial with one group which is without control group, 20 patients will receive acupuncture.

##### Settings and conduct

This study will be done on patients with refractory trigeminal neuralgia who will be referred to Oral & Maxillofacial Department of Shiraz Dental Faculty and Emam Reza clinic during 2018-2019. Sinew channel method of acupuncture will be accomplished for participants. No control group has been designed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The Patients with refractory trigeminal neuralgia since more than 3 months ago; The participants who sign the written consent form. Non inclusion criteria: Patients with Diabetes mellitus; Patients with cerebrovascular diseases; Patients with skin problems or hypersensitivity.

##### Intervention groups

The participants with refractory trigeminal neuralgia will receive acupuncture treatment. Sinew channel method of acupuncture will be accomplished for participants 3 sessions in a week for 10 sessions (3 weeks). The pharmacological treatment will continue during acupuncture therapy.

##### Main outcome variables

Visual analogue scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120101008585N8**

Registration date: **2019-05-24, 1398/03/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-05-24, 1398/03/03**

Update count: **0**

##### Registration date

2019-05-24, 1398/03/03

##### Registrant information

###### Name

Fatemeh Lavaee

###### Name of organization / entity

Shiraz Dental School

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1631 9309

###### Email address

lavaeef@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of acupuncture on pain of patients with trigeminal neuralgia

##### Public title

effect of acupuncture on trigeminal neuralgia pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

The Patients who have been under pharmacological treatment since at least 3 months ago for trigeminal neuralgia and they still suffer from pain The participants who sign the written consent form

**Exclusion criteria:**

The Patients who have been under pharmacological treatment since less than 3 months ago for trigeminal neuralgia Patients with Diabetes mellitus Patients with cerebrovascular diseases Patients who have any history of dermal skin problems or hypersensitivity

**Age**

From **15 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**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**

Shiraz University of Medical Sciences, Namazi square, Zand street, Shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7186781559

**Approval date**

2019-02-06, 1397/11/17

**Ethics committee reference number**

ir.sums.rec.1398.100

**Health conditions studied**

**1**

**Description of health condition studied**

trigeminal neuralgia

**ICD-10 code**

G50.0

**ICD-10 code description**

Trigeminal neuralgia

**Primary outcomes**

**1**

**Description**

Pain

**Timepoint**

Before intervention, before each session of 10 sessions of acupuncture

**Method of measurement**

Visual analogue scale

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: The patient in intervention group will receive acupuncture. Sinew channel method of acupuncture will be accomplished for participants, 3 sessions in a week for 10 sessions (3 weeks). The pharmacological treatment will continue for participants during acupuncture therapy. The pain severity of patients will be evaluated by visual analogue scale (VAS) in days 0,7,14,21. In sinew channel method the Ashi points, GB20, SJ5, ST40, ST36 will be used for acupuncture.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

School of Dentistry, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.Fateme Lavaee

**Street address**

Shiraz Dental School, Ghasrdasht street, Shiraz

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lavaeef@sums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Grant name**

**Grant code / Reference number**

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

empty

**Title of funding source**

**Proportion provided by this source**

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

### 2

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.Ghhasemi

**Street address**

Shiraz university of Medical Sciences, Zand street,  
Iran

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**Province**

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**Postal code**

7186782559

**Phone**

+98 71 3212 2438

**Email**

ghasemim@summs.ac.ir

**Grant name**

**Grant code / Reference number**

97-01-99-18108

**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 Lavaee

**Position**

Assistant Professor of Oral and Maxillofacial Medicine  
Department

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Shiraz School of Dentistry, Ghasrdasht street, Shiraz,  
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7186781559

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## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

### Contact

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Shiraz University of Medical Sciences

**Full name of responsible person**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All collected data will be shared after deidentification of participants.

**When the data will become available and for how long**

6 months after publication data will become available.

**To whom data/document is available**

The researchers in academic institutions.

**Under which criteria data/document could be used**

The researchers in academic institutions.

**From where data/document is obtainable**

The researchers in academic institutions can send their request to responsible person via email and request information

**What processes are involved for a request to access data/document**

The researchers in academic institutions can send their request to responsible person via email and request information

**Comments**