

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the therapeutic effect of Acupuncture as a complementary treatment in patients with Trigeminal neuralgia under medication treatment

#### Protocol summary

##### Study aim

Evaluation of the therapeutic effect of acupuncture  
Evaluation of the therapeutic effect of acupuncture for the treatment of patients with Trigeminal neuralgia

##### Design

Clinical trial with intervention and control groups in two groups of 8 people, with parallel groups, two-way blind, randomized as an individual block, the random function of Excel software was used for randomization The phase for this study does not apply

##### Settings and conduct

This trial was performed in patients referring to Al-Zahra Hospital affiliated to Isfahan University of Medical Sciences. Acupuncture was performed as a supplement to drug treatments. The intervention was performed on the main group and the placebo, which was the usual needles, was used to blind the control group. Participants, researchers, outcome assessors, and analyzers are blinded.

##### Participants/Inclusion and exclusion criteria

A person with typical symptoms of Trigeminal neuralgia includes sudden, unilateral, shock-like pain in the path of the Trigeminal nerve branches The person who with Trigeminal neuralgia undergoing drug treatment

##### Intervention groups

Perform acupuncture method in the intervention group  
Use the usual needles in the control group and apply pressure to the skin

##### Main outcome variables

Patient pain according to VAS criteria

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200704047996N1**

Registration date: **2020-07-25, 1399/05/04**

Registration timing: **retrospective**

Last update: **2020-07-25, 1399/05/04**

Update count: **0**

##### Registration date

2020-07-25, 1399/05/04

##### Registrant information

###### Name

ali kazemi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 4264 8448

###### Email address

alikalazemi\_dnt@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-09-22, 1395/07/01

##### Expected recruitment end date

2017-04-19, 1396/01/30

##### Actual recruitment start date

2016-09-22, 1395/07/01

##### Actual recruitment end date

2017-06-20, 1396/03/30

##### Trial completion date

2017-06-20, 1396/03/30

##### Scientific title

Evaluation of the therapeutic effect of Acupuncture as a complementary treatment in patients with Trigeminal neuralgia under medication treatment

##### Public title

Evaluation of the therapeutic effect of acupuncture as a complementary treatment in patients with trigeminal neuralgia under medication treatment

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

A person with typical symptoms of Trigeminal neuralgia includes sudden, unilateral, shock-like pain in the path of the Trigeminal nerve branches. The person who with Trigeminal neuralgia undergoing drug treatment

##### **Exclusion criteria:**

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

#### **Sample size**

Target sample size: **20**

Actual sample size reached: **16**

#### **Randomization (investigator's opinion)**

Not randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

Participants were blinded by contact of the needle with the skin as a placebo Patients' names were given to the out of study operator, who were randomly divided persons into two groups and each individual was assigned a separate code and provided with clinical care. After the intervention, the codes assigned to individuals In order to examine the consequences and the necessary analyzes, it was provided to the researcher and the evaluator of the consequence

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

###### **Street address**

Isfahan Dental School, Hakim Nezami St.,

##### **City**

isfahan

##### **Province**

Isfahan

##### **Postal code**

8514694171

##### **Approval date**

2016-06-14, 1395/03/25

##### **Ethics committee reference number**

3556405

### **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**

Patients' pain according to VAS criteria

##### **Timepoint**

Measurement of pain at the beginning of the study and after the end of the intervention after two weeks

##### **Method of measurement**

VAS criteria

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: In addition to previous drug treatment acupuncture was given once a day for 3 times a week for at least 2 weeks. Acupuncture was performed by an anesthesiologist who is proficient in this Method. Thin, disposable sterile steel needles were used. The needles were held in the muscle until a tingling sensation, such as numbness or electric shock, was felt in the area, and then remained in place for 30 minutes.

##### **Category**

Treatment - Other

#### **2**

##### **Description**

Control group: Continue previous medication and use regular needles to apply pressure to the skin

##### **Category**

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Al-Zahra Hospital of Medical Sciences, Isfahan

**Full name of responsible person**

iman mohamadi

**Street address**

Al-Zahra Hospital , Hakim Nezami St

**City**

isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

alzahra@mui.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

shaghayegh haghjoo javanmard

**Street address**

Isfahan University of Medical Sciences , Hezar Jarib St.

**City**

isfahan

**Province**

Isfahan

**Postal code**

۸۱۷۴۶۷۳۴۶۱

**Phone**

+98 31 3668 0048

**Email**

jazb@mui.ac.ir

**Web page address**

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

alikalzemi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

oral and maxillofacial

**Street address**

Isfahan Dental School, Hakim Nezami St.,

**City**

isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

alikalzemi\_dnt@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

alikalzemi

**Position**

resident

**Latest degree**

Specialist

**Other areas of specialty/work**

oral and maxillofacial

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## Person responsible for updating data

### Contact

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Esfahan University of Medical Sciences

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alikalzemi

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Medical doctor

**Other areas of specialty/work**

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**Email**

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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**

No - There is not 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**

Not applicable

**Data Dictionary**

Not applicable