Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
alikazemi_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

Isfehan

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
Isfehan
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
Isfehan
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
alikazemi
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
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
alikazemi_dnt@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
alikazemi
Position
resident
Latest degree
Specialist
Other areas of specialty/work
oral and maxillofacial
Street address
Isfahan Dental School, Hakim Nezami St.,
City
isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
alikazemi_dnt@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
alikazemi
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
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
alikazemi_dnt@yahoo.com

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