

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Orthokin therapy and radiofrequency ablation in the treatment for idiopathic trigeminal neuralgia

#### Protocol summary

##### Study aim

Determination of the effect of orthokin therapy and radioactive apparatus in the treatment of idiopathic trigeminal neuralgia

##### Design

A phase 3 randomized, two-arm, single-blinded, parallel-group trial of 46 patients. Randomization was carried out using random allocation software (RAS) with concealed randomization sequence

##### Settings and conduct

A total of 46 patients with idiopathic trigeminal neuralgia will be recruited from the outpatient clinic of Imam Reza Hospital in Tabriz and assigned to two groups using the block randomization method. The first group will be received the injection of 2 ml of orthokine, 4 times (once a week) each with a dose of 2 milliliters under fluoroscopic guide through the foramen oval with 22 spinal needles. The second group will be undergoing radiofrequency ablation under a fluoroscopic guide. Participants will be blinded to the random assignment of respondents until the end of the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of idiopathic trigeminal neuralgia, based on diagnostic criteria of the International Headache Association, trigeminal neuralgic pain, with an intensity of 40 to 100 based on the visual analog scale of 100 mm Exclusion criteria: Bleeding disorders, active infection, type 2 diabetes, patients with pacemakers, patients with internal drug injection devices, neoplasm, drug addiction, psychopathy, drug sensitivity, pregnancy and lactation

##### Intervention groups

Intervention group 1: Injection of 2 ml of orthokine, 4 times (once a week) each with a dose of 2 milliliters under fluoroscopic guide through foramen oval with 22 spinal needles Intervention group 1: Radiofrequency ablation under the fluoroscopic guide

##### Main outcome variables

Pain intensity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190618043923N6**

Registration date: **2022-07-17, 1401/04/26**

Registration timing: **retrospective**

Last update: **2022-07-17, 1401/04/26**

Update count: **0**

##### Registration date

2022-07-17, 1401/04/26

##### Registrant information

##### Name

Dawood Aghamohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3336 1928

##### Email address

aghamohammadi.d@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-04, 1400/12/13

##### Expected recruitment end date

2022-06-20, 1401/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Orthokin therapy and radiofrequency ablation in the treatment for idiopathic trigeminal neuralgia

#### Public title

Effect of Orthokin therapy and radiofrequency ablation in the treatment for idiopathic trigeminal neuralgia

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Confirmation of idiopathic trigeminal neuralgia, based on diagnostic criteria of the International Headache Association Trigeminal neuralgic pain, with an intensity of 40 to 100 based on the visual analog scale of 100 mm

##### Exclusion criteria:

Bleeding disorders Active infection Type 2 diabetes Patients with pacemaker Patients with internal drug injection devices Neoplasm Drug addiction Psychopathy Drug sensitivity Pregnancy and lactation

#### Age

From **18 years** old to **70 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **46**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Participants will be assigned to two groups using block randomization using random allocation software (RAS). The size of blocks is 4 including the equal numbers of each intervention of the study in each block and a 1:1 assignment ratio. Blocking will be performed by the non-involved person in data sampling and analysis. To conceal the assignment, the type of intervention will be written on a sheet of paper coding using the letters A and B and placed inside matted, consecutively numbered envelopes. The envelopes will be arranged according to the participants' entry into the intervention, and the type of group will be revealed.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The present study is a single-blinded study. Participants will not be aware of the random allocation sequences.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

3678965158

#### Approval date

2022-03-02, 1400/12/11

#### Ethics committee reference number

IR.TBZMED.REC.1400.1213

## Health conditions studied

### 1

#### Description of health condition studied

Idiopathic trigeminal neuralgia

#### ICD-10 code

G50.9

#### ICD-10 code description

Disorder of trigeminal nerve, unspecified

## Primary outcomes

### 1

#### Description

çain intensity

#### Timepoint

Pain intensity at the beginning of the study (before the intervention) and 7, 14 and 21 days after the start of intervention

#### Method of measurement

100-mm Visual Analogue Scale

### 2

#### Description

Analgesic consumption

#### Timepoint

Analgesic consumption at the beginning of the study (before the intervention) and 7, 14, and 21 days after the intervention

#### Method of measurement

Self-reported

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Injection of 2 ml of orthokine, 4 times (once a week) each with a dose of 2 milliliters under fluoroscopic guide through foramen oval with 22 spinal needles

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 1: Radiofrequency ablation under the fluoroscopic guide

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza hospital

##### Full name of responsible person

Dawood Aghamohammadi

##### Street address

Emam Reza hospital, Golgasht Str., Azadi Ave.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5163995479

##### Phone

+98 41 3336 1928

##### Email

daghamohamadi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Parviz Shahabi

##### Street address

Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

##### Phone

+98 41 3334 4280

#### Email

parvizshahabi@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Dawood Aghamohammadi

##### Position

Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Tabriz University of Medical Sciences, University Street

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## Person responsible for scientific inquiries

#### Contact

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Tabriz University of Medical Sciences

##### Full name of responsible person

Dawood Aghamohammadi

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

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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**

Undecided - It is not yet known if there will be a plan to  
make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to  
make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to  
make this available