# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Evaluation of the effect of autologous conditioned serum (Orthokine) injection into the oval foramen in pain control in trigeminal neuralgia patients: a pilot study

### Protocol summary

**Study aim**
Determination of the effect of autologous conditioned serum (Orthokine) injection into the Foramen ovale in controlling pain of trigeminal neuralgia patients
**Design**
One-armed open trial
**Settings and conduct**
A total of 10 patients with idiopathic trigeminal neuralgia will be enrolled in the palliative outpatient clinic of Emam Reza Hospital in Tabriz and will be treated with the Fluoroscopic guided injection of 2 milliliter autologous conditioned serum into the foramen ovale.
**Participants/Inclusion and exclusion criteria**
Inclusion criteria: diagnosis of idiopathic trigeminal neuralgia; complaining of severe pain refractory to oral medications Exclusion criteria: bleeding disorders; drug addiction; drug sensitivity; psychopathy
**Intervention groups**
Intervention: Injection of 2 milliliter autologous conditioned serum in to foramen oval, three times a week apart
**Main outcome variables**
Pain intensity

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20190618043923N1**
Registration date: **2019-06-29, 1398/04/08**
Registration timing: **prospective**

Last update: **2019-06-29, 1398/04/08**
Update count: **0**
**Registration date**
2019-06-29, 1398/04/08

**Registrant information**
**Name**
Dawood Aghamohammadi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2019-08-23, 1398/06/01
**Expected recruitment end date**
2020-02-18, 1398/11/29
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation of the effect of autologous conditioned serum (Orthokine) injection into the oval foramen in pain control in trigeminal neuralgia patients: a pilot study

**Public title**
The effect of autologous conditioned serum (Orthokine) in the treatment of trigeminal neuralgia
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Diagnosis of idiopathic trigeminal neuralgia Complaining of severe pain refractory to oral medications

**Exclusion criteria:**
Bleeding disorders Drug addiction Drug sensitivity Psychopathy

**Age**
From **19 years** old to **70 years** old

**Gender**
Both

**Phase**
1-2

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **10**

**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 Tabriz University of Medical Sciences

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

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
6987598632

**Approval date**
2019-05-20, 1398/02/30

**Ethics committee reference number**
IR.TBZMED.REC.1398.170

## 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 intensity

**Timepoint**
At the beginning of the study (before the intervention) and 7, 14, 21 and 28 days after the onset of the course of treatment

**Method of measurement**
Verbal rating scale ranges from 0 (no pain) to 10 (maximal pain)

### 2

**Description**
Pain duration

**Timepoint**
At the beginning of the study (before the intervention) and 7, 14, 21 and 28 days after the onset of the course of treatment

**Method of measurement**
Self-declaration

### 3

**Description**
Pain daily frequency

**Timepoint**
At the beginning of the study (before the intervention) and 7, 14, 21 and 28 days after the onset of the course of treatment

**Method of measurement**
Self-declaration

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Injection of 2 milliliter autologous conditioned serum into the foramen ovale following the fluoroscopy procedure after the injection of a safe contrast agent and approved place, three times a week apart. Fifty milliliters of ' blood will be drawn from ante-cubital vein of the patients into a blood bag and be transferred to an autoclaved centrifuge tube without anticoagulants. Blood will be incubated aseptically at 37 °C for 24 hours. After incubation the tubes will be centrifuged at 3500 rpm for 10 minutes to retrieve the autologous conditioned serum.

**Category**
Treatment - Other

## 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

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daghamohamadi@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
Abolghasem Jouyban

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

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research-vice@tbzmed.ac.ir

**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**
Associate professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Anesthesiology

**Street address**
Emam Reza hospital, Golgasht Str., Azadi Ave.

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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