

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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)

Phone

+98 41 3336 1928

Email address

aghamohammadi.d@tbzmed.ac.ir

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.

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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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