

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Investigation the effect of autologous conditioned serum (Orthokine) injection into the disc and intervertebral foramen on low back pain with radiculopathy caused by herniated intervertebral disc of the lumbar spine

#### Protocol summary

##### Study aim

Determining the effect of autologous conditioned serum (Orthokine) injection into the disc and intervertebral foramen on low back pain with radiculopathy caused by herniated intervertebral disc of the lumbar spine

##### Design

Three arm randomised trial with a parallel group design of 30 patients, enrolled between September 2019 and March 2020

##### Settings and conduct

A total of 30 patients with radicular low back pain caused by lumbar disc herniation in the outpatient clinic of Imam Reza Hospital in Tabriz were enrolled. They are then randomly assigned to three groups of study. The first group was treated with intradisc injection of autologous conditioned serum, the second group was treated with foraminal injection of autologous conditioned serum. The third group (control) received oral analgesic (diclofenac) with rest. The analgesic drug is a type of NSAIDs (diclofenac), which will be adjusted according to the morphine table.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: having a herniated disc between the lumbar vertebra confirmed by a magnetic resonance imaging; low back pain score between 40 and 80 points on the 100-mm pain visual analogue scale Exclusion criteria: bleeding disorders; drug addiction; drug sensitivity; psychopathy; history of surgery on spin; the lack of progressive motor weakness in the affected limb

##### Intervention groups

Group intervention 1: Intradisc injection of 2 milliliter autologous conditioned serum, three times a week apart in addition to oral pain relievers and rest Group intervention 2: Foraminal injection of 2 milliliter autologous conditioned serum, three times a week apart in addition to oral pain relievers and rest. Group intervention 3 (control): oral pain relievers (diclophenac)

and rest

##### Main outcome variables

Low back pain intensity within the past week

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190618043923N3**

Registration date: **2019-07-24, 1398/05/02**

Registration timing: **prospective**

Last update: **2019-07-24, 1398/05/02**

Update count: **0**

##### Registration date

2019-07-24, 1398/05/02

##### 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

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation the effect of autologous conditioned serum (Orthokine) injection into the disc and intervertebral foramen on low back pain with radiculopathy caused by herniated intervertebral disc of the lumbar spine

**Public title**

The effect of autologous conditioned serum on radiculopathy caused by herniated intervertebral disc

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having a herniated disc between the lumbar vertebra confirmed by a magnetic resonance imaging Low back pain score between 40 and 80 points on the 100-mm pain visual analogue scale

**Exclusion criteria:**

Bleeding disorders Drug addiction Drug sensitivity Psychopathy History of surgery on spin The lack of progressive motor weakness in the affected limb

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Permuted block randomization with block sizes of three and six and the allocation ratio of 1:1:1

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****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**

2019-05-20, 1398/02/30

**Ethics committee reference number**

IR.TBZMED.REC.1398.169

**Health conditions studied****1****Description of health condition studied**

Radioculopathy caused by lumbar disc herniation

**ICD-10 code**

M51.16

**ICD-10 code description**

Intervertebral disc disorders with radiculopathy, lumbar region

**Primary outcomes****1****Description**

Low back pain intensity within the past week

**Timepoint**

Pre-trial screening and at week 0 (baseline), 1, 2, 3 and 4 (follow-up sessions).

**Method of measurement**

100-mm visual analogue scale for low back pain

**2****Description**

Intensity of radiating pain in the lower extremities

**Timepoint**

Pre-trial screening and at week 0 (baseline), 1, 2, 3 and 4 (follow-up sessions).

**Method of measurement**

100-mm visual analogue scale for radiating pain

**3****Description**

Frequency of pain per day

**Timepoint**

Pre-trial screening and at week 0 (baseline), 1, 2, 3 and 4 (follow-up sessions).

**Method of measurement**

Self-reported

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Intradisc injection of 2 milliliter autologous conditioned serum following the fluoroscopy procedure after the injection of a safe contrast agent and approved place, one injection per week for 3 consecutive injection in addition to oral rescue medication up to 2000 mg/day (four 500-mg tablets) and 5000 mg/week (10 tablets) of acetaminophen (500 mg/tablet, Alborz Darou. Co., Ltd., Tehran, Iran) if they feel severe pain (> 60 mm on the 100-mm visual analogue scale). To prepare the autologous conditioned serum, 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. A clinical research coordinator will educate the participants in keeping a medication diary; he will also check the returned medications.

#### Category

Rehabilitation

### 2

#### Description

Intervention group 2: Foramenal injection of 2 milliliter autologous conditioned serum following the fluoroscopy procedure after the injection of a safe contrast agent and approved place, three times a week apart in addition to oral rescue medication up to 2000 mg/day (four 500-mg tablets) and 5000 mg/week (10 tablets) of acetaminophen (500 mg/tablet, Alborz Darou. Co., Ltd., Tehran, Iran) if they feel severe pain (> 60 mm on the 100-mm visual analogue scale). To prepare the autologous conditioned serum, 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. A clinical research coordinator will educate the participants in keeping a medication diary; he will also check the returned medications.

#### Category

Rehabilitation

### 3

#### Description

Control group: Oral rescue medication up to 2000 mg/day (four 500-mg tablets) and 5000 mg/week (10 tablets) of acetaminophen (500 mg/tablet, Alborz Darou. Co., Ltd., Tehran, Iran) if they feel severe pain (> 60 mm on the 100-mm visual analogue scale). A clinical research coordinator will educate the participants in keeping a medication diary; he will also check the returned medications.

## Category

Rehabilitation

## 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

Abolghasem Jouyban

##### Street address

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

##### City

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##### Province

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##### Postal code

6549832587

##### Phone

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##### Email

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

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**Email**  
daghamohamadi@yahoo.com

## 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

### Contact

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## Person responsible for updating data

### Contact

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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