

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)

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+98 41 3336 1928

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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

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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

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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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Person responsible for general inquiries

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