

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of intra-discal implantation of autologous adipose-derived mesenchymal stem cells in patients with chronic discogenic low back pain

Protocol summary

Study aim

The effect of intra-discal implantation of autologous adipose-derived mesenchymal stem cells in patients with chronic discogenic low back pain

Design

Clinical trial without control group, 10 patients sample size, Trial phase 2-3

Settings and conduct

Tertiary regional and teaching hospital. Participants including major eligibility criteria, among the patients who were candidates for intra-discal implantation of autologous adipose-derived mesenchymal stem cells referred to the Akhtar Hospital in 2019, 10 were selected by Sequential method. Intra-discal implantation of mesenchymal stem cells is done under fluoroscopic guidance at the pathology level. Main outcome measures (variables): Pain Level; Disability.

Participants/Inclusion and exclusion criteria

Aged 18 years and older; Chronic discogenic symptoms; Lack of response to traditional therapies; Pain based on VAS more than 4; Disability more than 30%

Intervention groups

Intervention group: Intra-discal implantation of autologous adipose-derived mesenchymal stem cells in the target area.

Main outcome variables

Pain Level; Disability.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131124015515N4**

Registration date: **2019-01-10, 1397/10/20**

Registration timing: **prospective**

Last update: **2019-01-10, 1397/10/20**

Update count: **0**

Registration date

2019-01-10, 1397/10/20

Registrant information

Name

Masoud Hashemi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2261 2252

Email address

dr.hashemi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intra-discal implantation of autologous adipose-derived mesenchymal stem cells in patients with chronic discogenic low back pain

Public title

Effect of Injection of Fat Stem Cells in Treatment of Lumbar Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 Patients older than 18 years; Signs of chronic discogenic pain for at least three months; Severity of pain based on VAS from 4 to above; Disability level of more than 30%; Failed to respond to traditional therapies; Local anesthetic infiltration in the facet joint / medial branches; Intervertebral disk degeneration with mean grade; Symptoms diagnostic disk with discography confirmation; Signed written informed consent to participate in the study

Exclusion criteria:
 History of lumbosacral surgery; Severe disc herniation; Spinal stenosis requiring surgery; Modic type III; Evidence of spinal anesthesia in MRI; Collapse of the disc space of over 50%; Uncontrolled blood pressure despite receiving appropriate treatment; Uncontrolled diabetes despite treatment Suitable; Other serious symptomatic diseases (cancers, autoimmune disease, blood disease, kidney, liver); Pregnancy; Lactation

Age
 From **18 years** old

Gender
 Both

Phase
 2-3

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 Shahid Beheshti University of Medical Sciences and Health Services

Street address

Tabnak St., Tehran, Tehran, Iran, Islamic Republic Of

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-12-08, 1397/09/17

Ethics committee reference number

IR.SBMU.REC.1397.045

Health conditions studied

1

Description of health condition studied

Chronic discogenic low back pain

ICD-10 code

M51.36

ICD-10 code description

Other intervertebral disc degeneration, lumbar region

Primary outcomes

1

Description

Pain Level

Timepoint

Before treatment, 1, 3, 6, 9 and 12 months after treatment

Method of measurement

visual analog scale (VAS) (0 None; 1-3 Mild; 4-7 Moderate; 8-10 Severe)

2

Description

Disability Level

Timepoint

Before treatment, 1, 3, 6, 9 and 12 months after treatment

Method of measurement

Oswestry Low Back Disability Questionnaire that disability is measured with 10 items. Each item is scored from 5-0, which indicates a higher score for the disability.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intra-discal implantation of autologous adipose-derived mesenchymal stem cells

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Seyed Masoud Hashemi MD

Street address

Pain Clinic, Akhtar Hospital, Sharifi Manesh st

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2261 2252

Email

dr.hashemi@sbmu.ac.ir

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Akhtar Hospital, Sharifi Manesh st.

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2261 2252

Email

dr.hashemi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi MD

Street address

Shahid Arabi st., Yaman St., Shahid Chamran Expressway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Masoud Hashemi MD

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Masoud Hashemi MD

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total potential data can be shared after unidentifiable people.

When the data will become available and for how long

Start the access period 12 months after printing the results

To whom data/document is available

Researchers working in scientific and academic institutions

Under which criteria data/document could be used

Perform further studies based on our study protocol

From where data/document is obtainable

Person responsible for scientific inquiries

What processes are involved for a request to access data/document

Send email

Comments