

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Safety evaluation of intra-discal transplantation of allogeneic clonal bone marrow derived mesenchymal stromal cells in patients with low back pain induced by degenerative disc disease: Interventional clinical trial, phase I

Protocol summary

Study aim

evaluation of the safety of intradiscal transplantation of Allogeneic clonal bone marrow derived mesenchymal stromal cells from healthy donor in patients with Discogenic Low Back Pain

Design

patients will enter the study in a regular order. the first patient is monitored for one month and if cell therapy is safe, the second and the third patients will enter the study and will be monitored. In case of no severe and life-threatening adverse effect the next patients will be included in the study.

Settings and conduct

location: Spine clinic of Yas hospital, operation room of Yas hospital clinical and paraclinical test before injection includes: physical examination , MRI and needed laboratory tests.

Participants/Inclusion and exclusion criteria

patients over 18 years of age with chronic discogenic low back pain whom have not responded to the common conservative management will enter the study willingly following signing the informed consent. Individuals with uncontrolled co-morbidities, any form of spine deformity, coagulopathy, opium and alcohol abuse, pregnancy and breast feeding will be excluded from the study.

Intervention groups

injection material: clonal mesenchymal stem cells derived from allogeneic bone marrow tissue injection rate: depending on the number of involved levels, intradiscal injection of one to two vials consisting of 9 million bone marrow-derived allogeneic mesenchymal cells suspension in 1 ml of normal saline with 1 ml of hyaluronic acid (brand name: Hyalo Brix)

Main outcome variables

no side effects, including short-term and long-term, systemic or local, and severe or mild, related and

unrelated to cell therapy (1 week and 1,3,6 months after the cell transplantation) by reviewing Common Terminology Criteria for Adverse Events version 5 (CTCAE v5)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080728001031N30**

Registration date: **2021-10-21, 1400/07/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-21, 1400/07/29**

Update count: **0**

Registration date

2021-10-21, 1400/07/29

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

nasser.aghdami@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety evaluation of intra-discal transplantation of allogeneic clonal bone marrow derived mesenchymal stromal cells in patients with low back pain induced by degenerative disc disease: Interventional clinical trial, phase I

Public title

Safety of intra-discal transplantation of allogeneic clonal bone marrow derived mesenchymal stromal cells in patients with low back pain induced by degenerative disc disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age more than 18 years both genders mild to moderate intervertebral disc degeneration in one to three levels Pfirrmann grade 3 to 6 (annulus fibrosus is able to maintain cell transplantation) Modic grade II or less in magnetic resonance imaging (MRI) with or without disc bulging lumbar pain visual analogue scale (VAS) : 3-9 back pain > radiculopathy Oswestry disability index (ODI):30-90 decrease in intervertebral disc height< 30% central disc bulging chronic back pain (atleast for three months in the last six months) which did not respond to symptomatic treatments including physical therapy and medication informed written consent

Exclusion criteria:

body mass index (BMI)>35 kg/m² Kellgren Knee osteoarthritis grading 3 or more inherited or acquired disease leading to spine deformation, which will impede cell transplantation segmental instability of spine, spine canal stenosis, spondylitis, spondylolisthesis, other spondyloarthropathies and other diseases that might interfere with the study prior history of disc surgery at the involved or adjacent levels any type of infections or lesions at the site of injection any issue in injection site that may make injection technically impossible prior history of intra-discal injection history of any type of epidural injection in the previous three months any type of neoplasm immuno-compromised or under treatment with immuno-suppressant agents disrupted hematological or biochemical laboratory results that causes contraindications for the intervention any type of coagulopathy or hemorrhagic disease or treatment with anticoagulants positive viral tests for HIV, CMV, HCV, HBV, HTLV 1&2 history or clinical diagnosis of severe osteoporosis known uncontrolled co-morbidities eg. diabetes(HbA1C>8%) or organ failure, liver (AST,ALT>100 U/L) kidney (Cr>2) and heart (EF<45%) movement disorders thyroid hormones disruption pregnancy or breast feeding opium or alcohol abuse history or clinical diagnosis of any type of psychosis allergy to substances that exist in culture media eg. gentamycin, bovine or horse serum

Age

From 18 years old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 5

Randomization (investigator's opinion)

Not randomized

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**

Research Ethics committees of Royan Institute-Academic center for education, culture and research

Street address

Royan Alley, Eastern Hafez St, Northern Banihashem St, 45 m Ghasem Soleymani Highway

City

tehran

Province

Tehran

Postal code

1951883831

Approval date

2021-07-13, 1400/04/22

Ethics committee reference number

IR.ACECR.ROYAN.REC.1400.040

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

chronic discogenic low back pain

ICD-10 code

M51.16

ICD-10 code description

Intervertebral disc disorders with radiculopathy, lumbar region

Primary outcomes

1

Description

no observed short-term or long term, systemic or local, severe or mild and related or unrelated to cell therapy adverse effects

Timepoint

before intervention, 1 week , 1, 3, 6 months after intervention

Method of measurement

by using CTCAE v5

Secondary outcomes

1

Description

decreased pain after injection

Timepoint

1, 3, 6 months after intervention

Method of measurement

visual analogue scale

2

Description

decrease of patient's disability after injection

Timepoint

1, 3, 6 months after injection

Method of measurement

Oswestry disability index

3

Description

improved quality of life after injection

Timepoint

6 months after injection

Method of measurement

36-item short Form Survey (SF-36)

4

Description

increased disc height after injection

Timepoint

6 months after injection

Method of measurement

MRI

5

Description

increased Apparent diffusion coefficient of intervertebral disc

Timepoint

6 months after injection

Method of measurement

DIFFUSION TENSOR IMAGING in MRI

6

Description

decrease in grading of disc degeneration

Timepoint

6 months after injection

Method of measurement

Scoring Pfirrmann using MRI

Intervention groups

1

Description

Intervention group: depending on the number of involved levels, intradiscal injection of one to two vials consisting of 9 million bone marrow-derived allogenic mesenchymal cells suspension in 1 ml of normal saline with 1 ml of hyaluronic acid (brand name: Hyalo Brix)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Masoud Vosough

Street address

Royan Alley, Eastern Hafez St, Northern Banihashem St, 45 m Ghasem Soleymani Highway

City

tehran

Province

Tehran

Postal code

1665664511

Phone

+98 21 2251 8388

Email

masvos@yahoo.com

2

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

Ramin Kordi

Street address

District 7, N Villa Rd

City

Tehran

Province

Tehran

Postal code

1598718311

Phone

+98 21 4216 0000

Email
yashospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
ATI tech pharmed
Full name of responsible person
Dr Masoud Vosough
Street address
Golbarg alley. Royan alley. E Hafez St. Bani Hashem
St. Soleimani Highway
City
tehran
Province
Tehran
Postal code
1665659911
Phone
+98 21 4022 3417
Email
masvos@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

ATI tech pharmed

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Royan Institute
Full name of responsible person
Mahtab Ahmadi pour
Position
researcher
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Royan Alley, Eastern Hafez St, Northern Banihashem
St, 45 m Ghasem Soleymani Highway
City
tehran

Province
Tehran
Postal code
1665664511
Phone
+2122518388
Email
mahtaab.ahmd@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Royan Institute
Full name of responsible person
Masoud Vosough
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
Royan Alley, Eastern Hafez St, Northern Banihashem
St, 45 m Ghasem Soleymani Highway
City
tehran
Province
Tehran
Postal code
1665664511
Phone
+2122518388
Email
masvos@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Royan Institute
Full name of responsible person
Hoda Madani
Position
researcher
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Royan Alley, Eastern Hafez St, Northern Banihashem
St, 45 m Ghasem Soleymani Highway
City
tehran
Province
Tehran
Postal code
1665664511
Phone
+21 22518388
Email

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