

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Safety of intradiscal injection of nucleus pulposus derived stromal cells in regeneration of human degenerated lumbar disc in patients with chronic low back pain

Protocol summary

Study aim

Evaluation of safety and efficacy of Nucleus pulposus ion-derived cell transplantation in the treatment of human degenerative intervertebral disc.

Design

Phase 1 clinical trial on 5 patients who underwent transplantation of nucleus pulposus-derived cells in the degenerative disc.

Settings and conduct

Nucleus pulposus tissue of patient is removed during surgery in Noor orthopedic clinic and sent to Royan Institute clean room for extraction and cell culture and then in the second surgery it will be transplanted to patients' degenerative disc in Noor clinic.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Degenerative intervertebral disc in one or two lumbar intervertebral discs with pain that has not responded to previous supportive therapies, including the use of conventional analgesics or physiotherapy within the last 6 months. Confirmation of fibrous ring integrity for cell implantation by MRI Reduction of the height of the intervertebral disc by 50% or more based on radiography. Do not have a vertebral infection. Exclusion criteria: Symptoms of a local infection at the site of the spine or viral illnesses such as hepatitis and AIDS Allergy to compounds such as bovine serum, gentamicin or horse serum Localized spinal imbalance, spinal canal stenosis, ischemic pathology, or other conditions that may adversely affect the study. Severe bone marrow changes due to intervertebral disc degeneration called Modic 3. Neoplasia

Intervention groups

A group receiving intradiscal transplantation of 20 million autologous nucleus pulposus-derived cells

Main outcome variables

Clinical examination, evaluation of complications of surgery or aspiration

General information

Reason for update

The assessment of annulus fibrosus (AF) integrity was based on MRI findings instead of discography. This decision was made following the recommendation of expert clinicians at the Royan Institute, considering both the comprehensive diagnostic capability of MRI for disc evaluation and the ethical concerns associated with discography as an additional invasive procedure.

Acronym

IRCT registration information

IRCT registration number: **IRCT20080728001031N35**

Registration date: **2022-10-08, 1401/07/16**

Registration timing: **retrospective**

Last update: **2025-07-15, 1404/04/24**

Update count: **1**

Registration date

2022-10-08, 1401/07/16

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

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell Biology and Technology

Expected recruitment start date

2017-12-25, 1396/10/04

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

2021-04-27, 1400/02/07

Actual recruitment end date

2021-07-23, 1400/05/01

Trial completion date

2022-08-22, 1401/05/31

Scientific title

Safety of intradiscal injection of nucleus pulposus derived stromal cells in regeneration of human degenerated lumbar disc in patients with chronic low back pain

Public title

Chronic low back pain nucleus pulposus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 and 65 years Of both sexes
 Degenerative intervertebral disc in one or two lumbar intervertebral discs with pain that has not responded to previous supportive therapies, including the use of conventional analgesics or physiotherapy within the last 6 months. Confirmation of fibrous ring integrity for cell implantation by magnetic resonance imaging (MRI)
 Reduction of intervertebral disc height by 50% or more based on radiography. Do not have a vertebral infection. Have no uncontrolled chronic underlying disease that is prohibited for treatment. Have no uncontrolled chronic underlying disease that is prohibited for treatment. Do not be pregnant or breastfeeding women. Not positive and transmissible viral infection.

Exclusion criteria:

infection signs or positive serology for HIV, hepatitis and syphilis allergy to gentamicin, or to bovine, cattle or horse serum congenital or acquired disease leading to spine deformities that may upset cell application spinal segmental instability, spinal canal stenosis, isthmus pathology, and other conditions that may compromise the study
 modic 3 changes on MRI images overweight with body mass index greater than 30.5 neoplasia immunosuppression participation in another clinical trial or treatment with another investigational product within 30 days prior to inclusion in the study other conditions that may, according to medical criteria, discourage participation in the study.

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

1

Groups that have been masked

No information

Sample sizeTarget sample size: **5**Actual sample size reached: **5****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 Royan infertility institute

Street address

Eastern Hafez St, Northern Banihashem St, 45 m
 Resalat highway

City

Tehran

Province

Tehran

Postal code

148- 16635

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.ACECR.ROYAN.REC.1394.36

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

chronic low back pain

ICD-10 code

M51.1

ICD-10 code description

Lumbar and other intervertebral disc disorders with
 radiculopathy

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

Clinical examination

Timepoint

1- Within one month after discharge every week

Method of measurement

1- Within one month after discharge every week:
 Responsible: Specialist: Action plan: Clinical examination,
 examination of complications of surgery or aspiration

2

Description

evaluation of complications of surgery or aspiration

Timepoint

2-6 weeks after injection

Method of measurement

2-6 weeks after injection: Responsible: Specialist: Action plan: Clinical examination, examination of complications of operation or aspiration

Secondary outcomes

1

Description

Clinical examination and evaluation of the safety

Timepoint

Three months after injection

Method of measurement

Three months after injection: Responsible: Physician specializing in measures: Evaluation of treatment safety by evaluating questionnaires for examination of complications and clinical examinations

2

Description

blood and urine tests

Timepoint

6 months after injection

Method of measurement

six months after injection: Responsible: Physician specializing in measures blood and urine tests

3

Description

The effect of treatment by MRI

Timepoint

one year after injection

Method of measurement

one year after injection: Responsible: specialist doctor
Measures assessment of the effectiveness of treatment by MRI

Intervention groups

1

Description

Injection of stem cells derived from the intervertebral disc

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Cell Therapy Center

Full name of responsible person

Nasser Aghdami

Street address

No. 9, Shaghayegh Alley, North Bani Hashem St.,
Shahid Soleimani Highway (Resalat), Tehran

City

Tehran

Province

Tehran

Postal code

1951883831

Phone

+98 21 2251 8388

Email

Regmed.department@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Massoud Vosough

Street address

Eastern Hafez St, Northern Banihashem St, 45 m
Resalat highway

City

Tehran

Province

Tehran

Postal code

1951883831

Phone

+98 21 2251 8388

Email

Regmed.department@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Royan Institute

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

Royan Institute

Full name of responsible person

Massoud Vosough

Position

M.D/ Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Eastern Hafez St, Northern Banihashem St, 45 m
Resalat highway

City

Tehran

Province

Tehran

Postal code

148- 16635

Phone

+98 21 2251 8388

Fax

Email

masvos@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Nasser Aghdami

Position

M.D/ Ph.D

Latest degree

Medical doctor

Other areas of specialty/work

Street address

Eastern Hafez St, Northern Banihashem St, 45 m
Resalat highway

City

Tehran

Province

Tehran

Postal code

1665664511

Phone

+98 21 2251 8388

Fax

Email

nasser.aghdami@royaninstitute.org

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iranian academic center for education culture and
research

Full name of responsible person

Hoda Madani

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

No. 9, Shaghayegh Alley, North Bani Hashem St.,
Shahid Soleimani Highway (Resalat), Tehran

City

Tehran

Province

Tehran

Postal code

1665664511

Phone

+98 21 2251 8388

Fax

Email

hoda62_m@yahoo.com

Web page address

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