Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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

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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 gentanicin, 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 stenos, 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.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target 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 Measurs 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
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Province
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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

M.D/ Ph.D

Latest degree

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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

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

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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