

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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.

**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**

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### **Province**

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### **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

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#### **Province**

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+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**

Nasser Aghdami

**Position**

M.D/ Ph.D

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**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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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