

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the safety of allogeneic human Wharton's jelly-derived mesenchymal stem cell transplantation in patients with lumbar degenerative disc disease: a phase I clinical trial

Protocol summary

Study aim

Evaluation of the safety of allogeneic human Wharton's jelly-derived mesenchymal stem cell transplantation in patients with lumbar degenerative disc disease: a phase I clinical trial

Design

Phase I clinical trial with one treatment group on 10 patients

Settings and conduct

Stem cell extraction: Knowledge-based production and research company, SinaCell; Stem cell injection: Pourcina Medical and Educational Center, Rasht

Participants/Inclusion and exclusion criteria

10 patients with bulging type of lumbar degenerative disc disease will be included in this study according to the inclusion and exclusion criteria. Written informed consent will be obtained from all the patients. Some inclusion criteria: Male or females between 18 and 60 years of age; Degenerative disease of one or two lumbar discs with predominant back pain after conservative treatment (physical and medical) for over 6 months; Patients with back pain and radicular pain. Some exclusion criteria: Pregnant or lactating women; Severe coagulation disorders or use of oral anticoagulants; Current or previous history of neoplasm in the last 3 years; Immunosuppressive therapy and corticosteroids.

Intervention groups

Intradiscal injection of a vial containing 10 million allogeneic Wharton's jelly-derived mesenchymal stem cells in 1 cc of normal saline

Main outcome variables

Safety and tolerability evaluation up to one year; Physical examinations including clinical examination and questionnaires for pain, disability and quality of life, adverse events and paraclinical test results (e.g., CBC count, ESR, CRP, and MRI) at 1, 3, 6 and 12 months.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211021052828N3**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Elham Vojoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 13 3376 4270

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-05, 1402/06/14

Expected recruitment end date

2024-01-04, 1402/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the safety of allogeneic human Wharton's jelly-derived mesenchymal stem cell transplantation in patients with lumbar degenerative disc disease: a phase I clinical trial

Public title

Safety and efficacy of umbilical cord Wharton's jelly-derived mesenchymal stem cell in patients with lumbar degenerative disc disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male or females between 18 and 60 years of age
Degenerative disease of one or two lumbar discs with predominant back pain after conservative treatment (physical and medical) for over 6 months
Patients with back pain and radicular pain
Fibrous ring capable of holding the cell implantation, demonstrated by RMI image (stages 2, 3 and 4 of Adams)
Decrease of disc height of more than 20% compared to the adjacent normal disc based on radiographic evaluation
Absence of spinal infection
Pfarrmann grade III-IV
The patient has the ability to understand the requirements of the study, to provide written informed consent, and to comply with the study protocol
In fertile women with a negative pregnancy test result and acceptance of appropriate methods of contraception
Lumbar degenerative disc disease with posterior bulging disc confirmed on MRI
Pre-treatment baseline low back pain of at least 40 mm on a 100 mm visual analog scale
Pre-treatment baseline Oswestry Disability Index Questionnaire score of at least 30 on the 100-point questionnaire
No previous history of spine surgery
No history of metabolic, autoimmune (e.g., rheumatoid arthritis) and genetic disease

Exclusion criteria:

Allergy to bovine serum, penicillin or dimethyl sulfoxide (DMSO)
Rejection of surgical treatment
Congenital or acquired diseases leading to spine deformations that may upset cell application
Spinal segmental instability, spinal canal stenosis, isthmus pathology and other conditions that may compromise the study
Modic III changes on MRI images
Overweight with body mass index (BMI) greater than 35
Pregnant or lactating women, or women planning to become pregnant during the first year (12 months) following cell injection
Current or previous history of neoplasm in the last 3 years (excluding basal cell carcinoma)
Immunosuppressive therapy and corticosteroids
Systemic inflammatory disease (spondylitis, rheumatoid arthritis, etc.)
Psychosis and severe personality disorder
Potentially active neurological disorder associated with symptoms (e.g., peripheral neuropathy)
History or current evidence of alcohol or drug abuse or recreational use of illicit drugs or prescription medications
High surgical risk (ASA> IV), or contraindication to anesthesia
Previous chemotherapy
Uncontrolled hypertension despite receiving optimal medication
A patient who has received a lumbar epidural steroid injection within 3 weeks prior to cell injection
History of receiving stem/progenitor cell therapy or other biological interventions to repair the target intervertebral disc
Participation in another clinical trial or treatment

with another investigational product within 30 days prior to inclusion in the study
Severe coagulation disorders or use of oral anticoagulants
Contraindications to MRI (history of implantation of cardiovascular and cerebrovascular stents, pacemakers, etc.)
Patients who are at risk of surgery in the next 6 months
An acute fracture of the spine at the time of enrollment in the study
Signs of infection or positive serology for HIV, hepatitis, CMV, or syphilis
Recent history of smoking
Subjects with severe osteoporosis (with an average T-score of -2.5 or below in the lumbar bone density test)
Serious pre-existing medical conditions such as cardiovascular disease, renal disease, liver disease, endocrine disease, cancer, and diabetes mellitus
Abnormal blood tests: hepatic (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST] >1.5 × upper limit of normal [ULN]), anemia or platelet count of <100 × 10⁹/L

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

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**

Research Ethics Committees of Guilan University of Medical sciences

Street address

The old building of the Faculty of Health, in front of 17 Shahrivar Hospital, Namjoo St., Shahid Siadati St.

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2023-08-09, 1402/05/18
Ethics committee reference number
IR.GUMS.REC.1402.265

Health conditions studied

1

Description of health condition studied

Lumbar degenerative disc disease

ICD-10 code

M51.1+

ICD-10 code description

Lumbar and other intervertebral disc disorders with radiculopathy

Primary outcomes

1

Description

Safety and tolerability assessment

Timepoint

Up to 1 year

Method of measurement

Clinical examination, questionnaire, and blood tests

2

Description

Physical examinations, side effects of treatment, and paraclinical test results (such as CBC count, ESR, CRP, and MRI)

Timepoint

Baseline and 1, 3, 6, and 12 months after intervention

Method of measurement

Clinical examination, questionnaires for pain, disability and quality of life, and paraclinical tests

Secondary outcomes

1

Description

Improvement in Visual Analogue Scale (VAS) for pain

Timepoint

Baseline and 1, 3, 6, and 12 months after intervention

Method of measurement

According to the patient's report

2

Description

Improvement in Oswestry Disability Index (ODI)

Timepoint

Baseline and 1, 3, 6, and 12 months after intervention

Method of measurement

Questionnaire

3

Description

Improvement in quality of life

Timepoint

Baseline and 6 and 12 months after intervention

Method of measurement

SF-36 questionnaire

4

Description

Improvement in disc height index (DHI)

Timepoint

Baseline and 6 and 12 months after intervention

Method of measurement

MRI

5

Description

Changes in the signal intensity of the nucleus pulposus (NP) region

Timepoint

Baseline and 6 and 12 months after intervention

Method of measurement

MRI

6

Description

Changes in the Pfirrmann grading

Timepoint

Baseline and 6 and 12 months after intervention

Method of measurement

MRI

7

Description

Assessment of worsening of patients' primary symptoms or performance (will be considered an AE)

Timepoint

Up to 1 year

Method of measurement

Clinical examination, questionnaires for pain, disability and quality of life, and paraclinical tests

Intervention groups

1

Description

Intervention group: Intradiscal injection of Wharton's jelly-derived mesenchymal stem cells to 10 patients with lumbar degenerative disc disease

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Medical and Educational Center, Rasht

Full name of responsible person

Cyrus Emir Alavi

Street address

Poursina Crossroads, Namjoo St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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Grant name

Rasht University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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Grant name

Rasht University of Medical Sciences

Grant code / Reference number

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

No

Title of funding source

private

Proportion provided by this source

50

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Elham Vojoudi

Position

Assistant Professor, Guilan University of medical
sciences

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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Person responsible for scientific inquiries

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Person responsible for updating data

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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