Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Pfirrmann 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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 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