

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Safety and efficacy of placental mesenchymal stem cells-derived exosomes in severe refractory inflammatory bowel disease patients

Protocol summary

(based on clinical and laboratory tests).

Study aim

Evaluating of safety and efficacy of placental mesenchymal stem cells-derived exosomes in alleviating symptoms in severe refractory inflammatory bowel disease patients

Design

Clinical trial without control group, without randomization, open label, sample size: 12, considering attrition: 15, phase I and II

Settings and conduct

Patients with severe refractory inflammatory bowel disease who refer to Tajrish Martyrs Hospital, on the first day, receive 3 vials of placental mesenchymal stem cells-derived exosome (equivalent to 1011 particles or 250-300 micrograms of exosomes) with an interval of 8 hours. Then a maintenance dose vial of exosome is injected daily on days 2, 3, 10 and 21. Then, from the first dose of exosome until 3 months after the injection of the last dose, clinical symptoms and laboratory tests will be assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ulcerative colitis and/or Crohn's disease for at least 6 months with refractory, or intolerance, or contraindication to use with monoclonal antibodies/Highly active Crohn's disease with a Crohn's disease index greater than 450 and/or a simple endoscopic score ≥ 8 (or ≥ 6 for isolated intestinal disease) Exclusion criteria: Using common immunomodulators in the past 4 weeks

Intervention groups

Intervention group: Injection of placental mesenchymal stem cells-derived exosomes: 3 of exosomes (equivalent to 1011 particles or 250-300 micrograms of exosome) on day 1, with an interval of 8 hours, then one vial of exosome maintenance dose daily on days 2, 3, 10 and 21 slowly (5 to 10 minutes) into the central vein

Main outcome variables

The percentage of patients who show adverse effects during or after exosome injection. Response to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230801058996N5**

Registration date: **2024-06-22, 1403/04/02**

Registration timing: **prospective**

Last update: **2024-06-22, 1403/04/02**

Update count: **0**

Registration date

2024-06-22, 1403/04/02

Registrant information

Name

Elham Roshandel

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5798 4000

Email address

elham.roshandel@sbm.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2027-07-23, 1406/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of placental mesenchymal stem cells-derived exosomes in severe refractory inflammatory bowel disease patients

Public title

Mesenchymal stem cells-derived exosomes in severe refractory inflammatory bowel disease patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ulcerative colitis and/or Crohn's disease for at least 6 months with refractory, or intolerance, or contraindication to use with monoclonal antibodies
Highly active Crohn's disease with a Crohn's disease index greater than 450 and/or a simple endoscopic score ≥ 8 (or ≥ 6 for isolated intestinal disease)

Exclusion criteria:

Using common immunomodulators in the past 4 weeks

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **12**

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 Shahid Beheshti University of medical Sciences

Street address

Aarabi street, Yaman street, Chamran highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2024-05-12, 1403/02/23

Ethics committee reference number

IR.SBMU.REC.1403.003

Health conditions studied

1

Description of health condition studied

Ulcerative colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

2

Description of health condition studied

Crohn's disease

ICD-10 code

K50

ICD-10 code description

Crohn disease

Primary outcomes

1

Description

The percentage of patients who show adverse effects during or after exosome injection.

Timepoint

From the first dose of exosome infusion until 3 months on days 7, 30, 60 and 90 after the last dose.

Method of measurement

Patient statements and medical team examinations in regular patient visits to the gastroenterology clinic for follow-up.

2

Description

Response to treatment (based on clinical and laboratory tests).

Timepoint

From the first dose of exosome infusion until 3 months on days 7, 30, 60 and 90 after the last dose.

Method of measurement

Regular patient examination in gastroenterology clinic for follow-up

Secondary outcomes

1

Description

Evaluating the progress of the disease using the Crohn's disease activity index for Crohn's disease and Myoscore for ulcerative colitis, the 36-item questionnaire for

improving the quality of life, measuring fecal calprotectin, CRP, short chain fatty acids, endoscopy and biochemical tests

Timepoint

From the first dose of exosome infusion until 3 months on days 7, 30, 60 and 90 after the last dose.

Method of measurement

Regular patient examination in gastroenterology clinic for follow-up

Intervention groups

1

Description

Intervention group: Injection of placental mesenchymal stem cells-derived exosomes: On day 1, 3 vials of exosomes (equivalent to 1011 particles or 250-300 micrograms of exosome) with an interval of 8 hours, then one vial of exosome maintenance dose daily on days 2, 3, 10 and 21 slowly (5 to 10 minutes) into the central vein

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish hospital

Full name of responsible person

Ali Pirsalehi

Street address

Tajrish Square, Shahdari Street

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<https://shmc.sbmu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Aarabi street, Daneshjou Boulevard, Velenjak

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<https://sbmu.ac.ir/>

Grant name

Grant code / Reference number

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

No

Title of funding source

Javidan Motaher Charity Foundation of Tehran

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

Other

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Grant code / Reference number

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

No

Title of funding source

Pharmed Behin Azma
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Elham Roshandel
Position
Associate professor استادیار
Latest degree
Ph.D.
Other areas of specialty/work
Cell therapy
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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the confidentiality of patient information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Evaluating the progress of the disease using the Crohn's disease activity index for Crohn's disease and Myoscore for ulcerative colitis, the 36-item questionnaire for improving the quality of life, measuring fecal calprotectin, CRP, short chain fatty acids, endoscopy and biochemical tests from the first dose of exosome infusion until 3 months on days 7, 30, 60 and 90 after the last

dose regular patient examination in gastroenterology clinic for follow-up

When the data will become available and for how long

Data files would be accessible after publication.

To whom data/document is available

Data files would be accessible to both academic researchers and industrial developers.

Under which criteria data/document could be used

Access to the data file will be provided for academic researchers to study. Data analysis is possible for use in meta-analysis review articles. Authentication of the applicant and provision of an academic email is required to access the data file.

From where data/document is obtainable

To receive the data file, please refer to the person in charge of the trial (Dr. Elham Roshandel): E-mail: elham.roshandel@gmail.com Phone number: 00982123031658 Address: Hematopoietic stem cell research center, Yas administrative complex, 4th floor, Taleghani Hospital, Aarabi street, Yaman street, Chamran highway, Tehran.

What processes are involved for a request to access data/document

The applicant must state his/her request accurately and completely. The requested data will be provided within ten working days after receiving the request.

Comments