

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Safety of injection of placental mesenchymal stem cell derived exosomes for Treatment of resistant perianal fistula in Crohn's patients

Protocol summary

Study aim

Evaluation of the effectiveness of exosome therapy in the healing of fistulas 3 and 6 months after injection

Design

Parallel, single blinded, 2 groups, 20, clinical trial phase I and II

Settings and conduct

This study will be performed in the colorectal surgery department at Imam Khomeini Hospital (Tehran University of Medical Sciences)

Participants/Inclusion and exclusion criteria

Inclusion criteria Patient with Crohn or other IBD disease, resistance to a 6 month period of treatment with anti TNF, without any success Patient with Crohn or other IBD disease, resistance to a 6 month period of treatment with infliximab, without any success Patient with Crohn or other IBD disease, resistance to a 6 month period of treatment with infliximab and anti TNF, without any success Patient with Crohn or other IBD disease, resistance to a 6 month period of drug therapy and surgery, without any success Exclusion criteria Patients with immunodeficiency disorders/disease Patients with history of malignancy Patient dissatisfaction Patients in need of surgery Severe co-morbidities (e.g., renal failure, liver failure, etc.) Cerebral Damage

Intervention groups

the injection of exosome

Main outcome variables

- Evaluation of clinical improvement of fistula in patients with Crohn's disease administrated with placental MSCs-derived exosomes in 3 and 6 months after injection. - Comparison fistula healing in patients with control using MRI data treating with placental MSCs-derived exosomes in 3 and 6 months after injection. - Evaluation the recurrence rate of fistula in Crohn's patients with treating with placental MSCs-derived exosomes in 3 and 6 months after injection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200413047063N3**

Registration date: **2021-09-03, 1400/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-03, 1400/06/12**

Update count: **0**

Registration date

2021-09-03, 1400/06/12

Registrant information

Name

Masoud Soleimani

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4508

Email address

soleimani.masoud@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-31, 1400/05/09

Expected recruitment end date

2022-07-31, 1401/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety of injection of placental mesenchymal stem cell derived exosomes for Treatment of resistant perianal fistula in Crohn's patients

Public title

Safety of injection of placental mesenchymal stem cell derived exosomes for Treatment of resistant perianal fistula in Crohn's patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with Crohn or other IBD disease, resistance to a 6 month period of treatment with anti TNF, without any success Patient with Crohn or other IBD disease, resistance to a 6 month period of treatment with infliximab, without any success Patient with Crohn or other IBD disease, resistance to a 6 month period of treatment with infliximab and anti TNF, without any success Patient with Crohn or other IBD disease, resistance to a 6 month period of drug therapy and surgery, without any success

Exclusion criteria:

Patients with immunodeficiency disorders/disease Patients with history of malignancy Patient dissatisfaction Patients in need of surgery Severe co-morbidities (e.g., renal failure, liver failure, etc.) Cerebral Damage

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 20

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

Iman Khomeini Hospital Complex Committee for

Ethics in Biomedical Research- Tehran University of Med

Street address

Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2021-08-04, 1400/05/13

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.184

Health conditions studied

1

Description of health condition studied

Crohn Patients with fistula

ICD-10 code

K50.013

ICD-10 code description

Crohn's disease of small intestine with fistula

Primary outcomes

1

Description

the size of fistula tract

Timepoint

Investigating the fistula healing after 3 and 6 month after injection

Method of measurement

MRI imaging

Secondary outcomes

empty

Intervention groups

1

Description

In a single-arm clinical trial, 6 patients with Crohn disease with perianal fistula are enrolled according to inclusion criteria; after the patients written consent, the patient will receive a dose of mesenchymal derived stem cell exosome (extracted the same protocol used in previous studies), the exosome will be injected in the tract of the fistula weekly for three weeks, and the patients will be monitored closely for adverse and allergic reactions for 3months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences, Imam hospital complex

Full name of responsible person

Dr. Seyed Mohsen Ahmadi Tafti

Street address

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2

Recruitment center

Name of recruitment center

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Omid cell and tissue Company

Full name of responsible person

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Street address

No 12, Edvard Brown alley, North Kargar

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Omid cell and tissue Company

Proportion provided by this source

80

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

Tehran University of Medical Sciences

Full name of responsible person

seyed Mohsen Ahmadi Tafti

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Masoud Soleimani

Position

professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Hojjatollah Nazari

Position

Research assistant

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Safety of injection of placental mesenchymal stem cell derived exosomes for Treatment of resistant perianal fistula in Crohn's patients

When the data will become available and for how long

late 2021

To whom data/document is available

scientific community including medical society and stem cell researchers

Under which criteria data/document could be used

the criteria mentioned in this request

From where data/document is obtainable

direct email

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

one-three week period

Comments