Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Squre, 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

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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
Masoud Soleimani

Street address
No 12, Edvard Brown alley, North Kargar

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Soleim_m@modares.ac.ir

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

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Position
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Hematology

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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

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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