

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of the safety and efficacy of the injection of placenta-derived mesenchymal stromal/stem cell exosomes with and without priming with TNF- α in patients with complex perianal fistula without a history of CHRONS disease: A double-blinded randomized controlled trial

Protocol summary

Study aim

Evaluation of the safety and efficacy of human placental stromal/mesenchymal stem cells-derived exosomes treated with TNF- α in patients with perianal fistula without underlying disease

Design

Clinical trial with the control group, with factorial groups, double-blind, randomized, phase 1 on 30 patients. The rand function of Excel software was used for randomization.

Settings and conduct

The method of implementing this study (all steps will be done Shariati Hospital): - Receiving placenta samples - Isolation of mesenchymal stem cells from the placenta based on GMP and their characterization - Priming with TNF- α - Preparing and collecting Conditioned Media - Isolation of exosomes - Exosome characterization - Exosome injection - Follow-up of patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: sign the informed consent, Patients with complex perianal fistula aged 18-75, Acceptable general health Exclusion criteria: Patients with underlying diseases that affect the pathophysiology of perianal fistula

Intervention groups

1- The first group will receive the conventional seton along with normal saline injection as a control group for the exosome groups. 2- The second group will receive seton plus injection of untreated exosomes (as a control group for treated exosomes). The number of injections in this group will be 1 time. 3- The third group will receive seton plus an injection of treated exosomes. The number of injections in this group will be 1 time.

Main outcome variables

به رده‌های مختلف; بیان MSC تمایز MSC; مورفولوژی سلول‌های سطح سلول; بیان مارکر CD45 سطح سلول; بیان مارکر CD34 مارکر

سطح سلول; بیان مارکر CD90 سطح سلول; بیان مارکر CD44
ها; توزیع سایز MSC زنده‌مانی; TNF- α ; سطح سلول CD105
در بیماران CBC; آگزوزوم‌ها; غلظت پروتئین محلول حاوی آگزوزوم‌ها
بیماران; اندکس‌های Calprotectin; در بیماران ESR; در بیماران CRP
(EUA) بهبود در معاینات تحت بیهوشی

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240128060828N1**

Registration date: **2024-02-02, 1402/11/13**

Registration timing: **prospective**

Last update: **2024-02-02, 1402/11/13**

Update count: **0**

Registration date

2024-02-02, 1402/11/13

Registrant information

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Hossein Bagheri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the safety and efficacy of the injection of placenta-derived mesenchymal stromal/stem cell exosomes with and without priming with TNF- α in patients with complex perianal fistula without a history of CHRON'S disease: A double-blinded randomized controlled trial

Public title

Investigating the effect of stromal/mesenchymal stem cell-derived exosomes in patients with perianal fistula

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

sign the informed consent Patients with complex perianal fistula aged 18-75 Acceptable general health of patients based on physical tests and medical history (absence of diseases or disorders that may interfere with the treatment method evaluated in this study)

Exclusion criteria:

Patients with underlying diseases that affect the pathophysiology of perianal fistula (including IBD, rectovaginal fistula or acute sepsis, uncontrolled diabetes, and active or latent HIV, HBV, or HCV infection) Patients who need perianal surgery for reasons other than fistula Major surgeries within 28 days before admission Use of immune system modulators for reasons other than fistula in patients

Age

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

Gender

Both

Phase

1

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

RANDBETWEEN function of Excel software was used for randomization. In short, cells that contain patients with numbers 1 to 30 with the RANDBETWEEN function [fx = RANDBETWEEN(1, 30)] are selected, and patients are randomly assigned a number based on the mentioned groups. In this way, random numbers 1 to 10 are in the first group, numbers 10 to 20 are in the second group, and numbers 20 to 30 are in the third group.

Blinding (investigator's opinion)

Double blinded

Blinding description

During this study, the data analyst and the clinician will be blinded. The clinical doctor only received the vial of liquid without the description label, and the patient will be unaware of the type of injected substance (therapeutic or control substance).

Placebo

Used

Assignment

Factorial

Other design features

This study will be conducted as a phase 1 randomized controlled clinical trial in order to check the safety and effectiveness of the treatment method of this study in three groups and with the inclusion of 30 patients (10 patients in each group). During this study, blinding will be done in a double-blind manner, for this purpose, the specialist doctor and the patient will not know about the treatment method used. The groups will be as follows: 1- The first group will receive the conventional seton along with normal saline injection as a control group for the exosome groups. 2- The second group will receive seton plus injection of untreated exosomes (as a control group for treated exosomes). The number of injections in this group will be 1 time. 3- The third group will receive seton plus an injection of treated exosomes. The number of injections in this group will be 1 time.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of The Institute of Pharmaceutical Sciences -Tehran University of Medical

Street address

North Kargar Ave.

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Tehran

Postal code

1417933431

Approval date

2024-01-20, 1402/10/30

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.155

Health conditions studied**1****Description of health condition studied**

Perianal Fistula

ICD-10 code

K60.3

ICD-10 code description

Anal fistula

Primary outcomes

1

Description

Evaluation of any regional undesirable events

Timepoint

Within 48 to 72 hours

Method of measurement

In the form of a phone call and based on the patient's opinion

2

Description

Evaluation of any systemic undesirable events

Timepoint

Within 48 to 72 hours

Method of measurement

In the form of a phone call and based on the patient's opinion

3

Description

Degree of healing recorded by surgeon examination

Timepoint

Examination of the patient's condition during 6 months of follow-up

Method of measurement

by laboratory tests and especially during examination under anesthesia (EUA)

4

Description

Degree of self satisfaction and quality of life recorded by patients

Timepoint

After the termination of the follow-up of the patient's condition

Method of measurement

By using special questionnaires for the health context of 36-Item Short Form Survey (SF-36)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Seton (conventional treatment method of perianal fistula) plus injection of untreated exosomes-derived placenta mesenchymal stem cells (as a control group for treated exosomes). The number of injections in this group will be 1 time.

Category

Treatment - Other

2

Description

Intervention group: Seton plus injection of treated exosomes-derived placenta mesenchymal stem cells. The number of injections in this group will be 1 time.

Category

Treatment - Other

3

Description

Control group: conventional seton along with normal saline (as a control group for exosome groups). In order to reduce the difference between the treatment and control groups, it is also necessary to inject normal saline so that the therapeutic effect of the new combined approach can be relied upon.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

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Sponsors / Funding sources

1

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Grant name
Not available
Grant code / Reference number
کد و ردیف بودجه در حال حاضر مشخص نشده است.
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
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

Person responsible for general inquiries

Contact
Name of organization / entity
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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

Yes - There is 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

Not applicable

Title and more details about the data/document

Because the study is in the preliminary stage and if the study is done, the mentioned sections will be added.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

All scientists interested in research in this field

Under which criteria data/document could be used

If needed, the sections and documents not provided will be provided.

From where data/document is obtainable

Dr. Nasim Vosooghi - Phone Number: 009123724378 -

Email address: dr.n.vosoughi@gmail.com - Postal

Address: No. 87, Third floor, Building No.2, School of

Advanced Technologies in Medicine, Italia st, Keshavarz

blv. Tehran, Iran; Postal Code: 1417755469

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

After confirming the identity of the person, the documents/data will be provided as soon as possible after the request.

Comments