

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Safety and efficacy of Injection of Human Placenta Mesenchymal Stem Cells Derived Exosomes for treatment of complex Anal Fistula

Protocol summary

Study aim

1. Safety of Human Placenta Mesenchymal Stem Cells Derived Exosomes for treatment of complex Anal Fistula
2. Efficacy of Human Placenta Mesenchymal Stem Cells Derived Exosomes for treatment of complex Anal Fistula
3. Fistula changes in MR imagings, 12 weeks after treatment
4. Evaluation of quality of life in perianal fistula patient's questionair score before and 12 weeks after treatment

Design

Single group phase 2 of clinical trial design of 15 patients

Settings and conduct

Patients with complex perianal fistula referred to Imam Khomeini hospital, will be included in the study if they contain inclusion criteria. The fistula was evaluated by clinical examination and MRI and patients fill the quality of life questionair. Exosome injections are performed weekly for consecutive three weeks. Patients will reexamined and fill the questionair and MRI will done 12 weeks later. Recent findings will compare with the initial data. During this period, patients are examine for complications.

Participants/Inclusion and exclusion criteria

Inclusion Criteria : 1. Age between 18-70 years old
2. Occurrence of complex perianal fistula
3. Informed consent
Exclusion Criteria: 1. Active inflammatory bowel disease
2. Synchronous perianal abcess
3. Alcohol, narcotic and stimulant consumption
4. Having active Hepatitis B, C, HIV or TB
5. Pregnancy and lactation
6. Uncontrolled diabetes mellitus
7. Evidence of surgical cotraindication
8. Psychological disorders and noncooperative patient

Intervention groups

Human Placenta Mesenchymal Stem Cells Derived Exosomes injected in fistula tract of patients with complex perianal fistula in 3 weekly episodes and it's safety and efficacy was evaluated.

Main outcome variables

Discharge amount; External orifice reepithelialisation;

Inflammation, discharge and abcess larger than 2 cm in MR imaging; Quality of life questionair score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211212053361N1**

Registration date: **2021-12-22, 1400/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-22, 1400/10/01**

Update count: **0**

Registration date

2021-12-22, 1400/10/01

Registrant information

Name

Mohsen Ahmadi Tafti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1573

Email address

smahmadit@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of Injection of Human Placenta Mesenchymal Stem Cells Derived Exosomes for treatment of complex Anal Fistula

Public title

Safety and efficacy of exosome Injection in perianal fistula

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-70 years old Complex perianal fistula
Informed consent

Exclusion criteria:

Active inflammatory bowel disease Synchronous perianal abscess Alcohol, narcotic and stimulant consumption Having active hepatitis B,C, HIV or TB Pregnancy and lactation Uncontrolled diabetes mellitus Evidence of surgical contraindication Psychological disorders and noncooperative patient

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

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**

Biomedical Research Ethics Committee

Street address

Tohid square, Imam Khomeini hospital complex

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2021-12-01, 1400/09/10

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.360

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

Complex perianal fistula

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

discharge amount

Timepoint

before and during and 12 weeks after the study

Method of measurement

due to patient's history

2**Description**

External orifice reepithelialisation

Timepoint

before and 12 weeks after the study

Method of measurement

clinical examination and MRI

3**Description**

Inflammation and abscess larger than 2 cm

Timepoint

before and 12 weeks after the study

Method of measurement

MRI

4**Description**

Quality of life questionnaire score

Timepoint

before and 12 weeks after the study

Method of measurement

Quality of life questionnaire in perianal fistula patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital complex

Full name of responsible person

Seyed Mohsen Ahmadi Tafti

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar fotouhi

Street address

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Web page address

<https://vcr.tums.ac.ir/>

Grant name

Grant code / Reference number

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

Tehran University of Medical Sciences

Full name of responsible person

Seyed Mohsen Ahmadi Tafti

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

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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

Not applicable

Title and more details about the data/document

Questionnaires, Patient's data, MRI data, results, statistical analysis, Material and methods

When the data will become available and for how long

Just after article publication

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

using in metaanalysis

From where data/document is obtainable

Person responsible for scientific inquires

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

Communicate with corresponding author, E-mail adress: smahmadit@sina.tums.ac.ir

Comments