Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 reffered 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 compex 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.Peregnancy 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 perianalnal Fisula 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 perianalabcess 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 pateint

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 pateint'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 abcess larger than 2 cm
Timepoint
before and 12 weeks after the study
Method of measurement
MRI

4

Description
Quality of life questionair score
Timepoint
before and 12 weeks after the study
Method of measurement
Quality of life questionair 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
Tohid Square, Imam Khomeini Hospital complex
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Tehran
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smahmadit@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Akbar fotouhi
Street address
Tohid Square, Imam Khomeini hospital complex
City
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1419733141
Phone
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Email
smahmadit@sina.tums.ac.ir
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
Street address
Tohid Square, Imam Khomeini Hospital complex
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Person responsible for scientific inquiries

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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
Questionairs, 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