Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the difference between clinical repair and recurrence in patients with perianal fistula undergoing VAAFT surgery in two groups with and without exosome

Protocol summary

Study aim
To compare the rate of perianal fistula recurrence and the rates of clinical and radiological healing between patients receiving exosome therapy and those not receiving exosome therapy

Design
Patient will be randomly divided into two groups Intervention and Control group. Each group will consist of 20 patient. Block randomization wil be usead.

Settings and conduct
VAAFT surgery will be performed using the same standard procedure in both groups.the intervention group will receive 5 cc Exosome injection, while the control group will receive 5 cc of normal saline.The study will be designed as a Double blinde trial.the Physician and the Treatment team responsible will be unware of patients group allocation.the Patients will also be unware of the type of intervention they eeceive.

Participants/Inclusion and exclusion criteria
All patients with complex anal fistula who are treated using the VAAFT Age between 18 and 60 years absence of concomitant diseases (such as severe cardiovascular disease or active autoimmune diseases and IBD)

Intervention groups
Exosome injection during VAAFT in the intervention group No Exosome injection during VAFFT surgery in the control group

Main outcome variables
Reduction in recurrence and improvement in the healing process and treatment of Perianal fistula

General information

Reason for update

Acronym
VE

IRCT registration information
IRCT registration number: **IRCT20260915071064N1**
Registration date: **2026-09-22, 1405/06/31**
Registration timing: **prospective**

Last update: **2026-09-22, 1405/06/31**
Update count: **0**

Registration date
2026-09-22, 1405/06/31

Registrant information

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Amirhossein Rahmatnejad

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
2026-09-23, 1405/07/01

Expected recruitment end date
2026-10-22, 1405/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the difference between clinical repair and recurrence in patients with perianal fistula undergoing VAAFT surgery in two groups with and without exosome

Public title
Effect of Exosome in treatment of perianal fistula
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All paitients with complex anal fistula who undergo VAAFT as the surgical treatment modality Aged between 18 and 60 years Absence of serious comorbidities that could affect the outcomes (such as severe heart failure or active autoimmune diseases)
Exclusion criteria:
Patients with an active systemic infection or high grade fever at the time of surgery Patients with fistulas secondary to IBD Presence of malignancy at the fistulasite or in other organs Pregnancy or breastfeeding Failure to complete the 6 months follow up or unwillingness to participate in follow up assessments Use of immunosuppressive medications or biologic therapies within the previous 3 months Presence of uncontrolled medical conditions or diseases such as uncontrolled diabetes mellitus that may impair the healing process Presence of complications such as perianal sepsis or inability to undergo exosome injection
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
For patient randomization in this study, block randomization will be used to ensure an equal distribution of patients btween the study groups. In this methode, blocks of a fixed size (e.g.,blocks of 4 or 6) will be designed, and the allocation of patients to the intervention and control groups within each block will be determined randmly. This process will be performed using computuer generated randomization software to minimize any potenial allocation bias. To ensure allocation concealment, the randomization sequence will be generated by an independent individual who is not involved in the conduct of study. The allocation codes will be placed in sealed and sequentially numbered envelopes, which will be opened only after the patient has been enrolled in the study and has provided informed consent. This randomization method will help reduce selection bias in patient allocation and ensure a fair comparison between the study groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
To minimize study bias, the study will be designed as a double-blind study. The physician and the medical team responible for administering the intervention and assessing the outcomes will be unware of the patients allocation to the two study groups. In addition, the patients themselves will be unware of the typ of intervention they receive.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Imam Khomeini Hospital Complex of Tehran University of Medical Sciences
Street address
No 28, Biston Ave, Yusef abad
City
Tehran
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Tehran
Postal code
1431754333
Approval date
2025-07-29, 1404/05/07
Ethics committee reference number
IR.TUMS.IKHC.REC.1404.208

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
Percentage of patients with fistula recurrence
Timepoint
Assessment of recurrence at 3 and 6 month
Method of measurement
Examination and MRI

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group undergoing VAAFT surgery and Exosome injection. The intervention group will receive 5 cc of Exosome, prepared from a healty donor in the laboratory. Patient will undergo MRI imaging and clinical examination at 3 and 6 month after treatment to evaluate treatment outcomes.
Category
Treatment - Surgery

2

Description
Control group: The group undergoing VAAFT surgery without Exosome injection
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Amirhossein Rahmatnejad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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
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
Amirhossein Rahmatnejad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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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
All data can be shared after de-identifyding the individuals
When the data will become available and for how long
Access to the results after publication
To whom data/document is available
Access for researchers, universities and scientific institutions
Under which criteria data/document could be used
Use in research and scientific studies, as well as for medical purposes
From where data/document is obtainable
Dr Amirhosein Rahmatnejad
amirhoseinrahmatnejad@gmail.com
What processes are involved for a request to access data/document
Contact vai email and verfication of identity before granting access to the data
Comments