

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Assessment of Efficacy and Safety of the allogeneic adipose derived mesenchymal stem cells along with platelet rich fibrin in 24 patients with perianal fistulas: a phase 1 and 2 pilot randomized, single blinded trial

#### Protocol summary

##### Study aim

Evaluation of possible side effects including redness, local sensitivity, pruritus, anaphylaxis, pain, fever, localized exfoliation, and efficacy of treatment after injection of adipose derived stem cells with platelet rich fibrin in patients

##### Design

A phase 1 and 2 pilot clinical trial with a control group, single blinded and randomized on 12 patients. Block randomization method was used for randomization.

##### Settings and conduct

Patients with anal fistula who refer to Shahid Beheshti Hospital during the study will be included in the study if they are eligible.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Complex anal fistula (recurrent fistula, High Trans Sphincteric fistula, Supra Sphincteric fistula, Extra Sphincteric fistula, and Horse Shoe fistula) 2. Patient over 18 years old 3. Patients who are able to give informed consent Exclusion criteria 1. Patients with Crohn's disease, HIV, BGC infectious disease, and hepatitis 2. Simultaneous onset of several medically significant diseases (multifactorial) (Significant Medical Comorbidity) like active cardiac angina with uncontrolled diabetes (Active Cardiac Angina Uncontrolled Diabetes Mellitus) and Active Collagen Vascular Disease Renal and Hepatic Failure 3. Pregnancy or breastfeeding 4. Neoplasia or anorectal cancer 5. Addiction to alcohol and drugs 6. Undischarged anal fistula 7. Patients taking immunosuppressive drugs 8. Bone Marrow Dysfunction

##### Intervention groups

Control group. Patients with anal fistula treated by conventional surgical method. Intervention group. Patients with anal fistula will be treated with allogeneic MSCs with platelet-rich fibrin along with conventional surgery.

##### Main outcome variables

side effects, Wound healing and filling of the lesion after one month and six months of injection; No bleeding after one month and six months of injection; No swelling at the injection site

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210830052332N1**

Registration date: **2022-04-05, 1401/01/16**

Registration timing: **prospective**

Last update: **2022-04-05, 1401/01/16**

Update count: **0**

##### Registration date

2022-04-05, 1401/01/16

##### Registrant information

##### Name

Mohsen Sheykhasan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-30, 1401/06/08

##### Expected recruitment end date

2022-10-02, 1401/07/10

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Assessment of Efficacy and Safety of the allogeneic adipose derived mesenchymal stem cells along with platelet rich fibrin in 24 patients with perianal fistulas: a phase 1 and 2 pilot randomized, single blinded trial

**Public title**  
Assessment of the effect of allogeneic adipose derived mesenchymal stem cells along with platelet rich fibrin for perianal fistulas in treatment of perianal fistulas

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Complex anal fistula "recurrent fistula, high trans sphincteric fistula, supra sphincteric fistula, extra sphincteric fistula, and horseshoe fistula" patient who is older than 18 years of age Patients who can sign informed consent  
**Exclusion criteria:**  
Patients with Crohn's disease, HIV, BCG and hepatitis Significant Medical Comorbidity such as Active Cardiac Angina Uncontrolled Diabetes Mellitus and Active Collagen Vascular Disease Renal and Hepatic Failure Pregnancy or breastfeeding Neoplasia or anorectal cancer Alcohol and drug addiction Undischarged perianal fistula Patients taking immunosuppressive drugs Bone Marrow Dysfunction

**Age**  
From **19 years** old

**Gender**  
Both

**Phase**  
1-2

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **24**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, we will use the restricted randomization method of Block randomization type. The size of all blocks is equal and we will have quarter blocks "including 2 participants in the intervention group and 2 participants in the control group" in this two-group trial. The letter A will be assigned to the intervention group and the letter B to the control group, and in quarter blocks with the letters A and B, the six modes of AABB, ABAB, BBAA, BABA, BBAA, BAAB will be written on separate sheets and will be placed in an envelope. One of these sheets will be randomly brought out from the envelope, and the written composition on it will be noted and that sheet will be thrown back into the envelope. Since the sample size in this study is 12 patients, this

operation will be repeated 3 times, and each time the written composition on each sheet will be written in the composition sequence of the previous sheet. Then, for each of the letters, a number from one to twelve will be assigned according to the arrangement of the written letters in the sequence, and each letter will be placed inside an envelope and the number of that letter will be written on the envelope. Each time a patient is selected based on the inclusion criteria, one of these envelopes will be opened based on the order written on the envelope and it will be specified that the patient should be placed in the intervention or control group.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In order to eliminate the bias caused by the patient's awareness of the type of received treatment and its possible effect on the research results, the study is performed as a single blinded trial. Given that surgery is one of the therapeutic commonalities in both groups, it is natural that the patients are not aware of the injection of mesenchymal stem cells with platelet rich fibrin.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Research Ethics committee of Mashhad Academic Center for Education, Culture and Research

**Street address**

Academic center for education, culture and research (ACECR), Khorasan Razavi Province Branch, Azadi Sq, Daneshgah Campus, Khorasan Razavi province, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177949367

**Approval date**

2021-08-10, 1400/05/19

**Ethics committee reference number**

IR.ACECR.JDM.REC.1400.013

**Health conditions studied**

**1**

**Description of health condition studied**

perianal fistula

**ICD-10 code**

M25.18

**ICD-10 code description**

Fistula, other specified site

**Primary outcomes****1****Description**

Assessment of Efficacy and Safety allogeneic adipose derived mesenchymal stem cells along with platelet-rich fibrin for perianal fistula

**Timepoint**

One month and six months

**Method of measurement**

The clinical examination will be performed repeatedly by a specialist surgeon at intervals of the third day, the tenth day, the first month, the third month, and the sixth month. MRI evaluation will also be done in the sixth month. In addition, the length of hospital stay, infections, any other serious complications, and bleeding and their survival will be recorded. It should be noted that at time points of one month and six months after injection, in addition to reporting the results of the above parameters, CRP levels will be evaluated.

**Secondary outcomes****1****Description**

Wound healing

**Timepoint**

Six month

**Method of measurement**

Accurate measurement using digital calipers with an accuracy of one hundredth of a millimeter

**2****Description**

infection improvement in the wound area

**Timepoint**

Six month

**Method of measurement**

Examination of the wound site and history

**Intervention groups****1****Description**

Intervention group 1: a group in which patients with anal fistula will be treated with allogeneic mesenchymal stem cells along with conventional surgery.

**Category**

Treatment - Other

**2****Description**

Intervention group 2: a group in which patients with anal fistula will be treated with platelet-rich fibrin along with conventional surgery.

**Category**

Treatment - Other

**3****Description**

Intervention group 3: a group in which patients with anal fistula will be treated with allogeneic mesenchymal stem cells with platelet-rich fibrin along with conventional surgery.

**Category**

Treatment - Other

**4****Description**

Control group: a group in which patients with anal fistula will be treated with conventional surgery.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

**Full name of responsible person**

Dr. Seyed Jalal Eshaq Hoseini

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Shahid Beheshti Blvd, Qom

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j.hosseini@muq.ac.ir

**Web page address**<https://bmc.muq.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

Dr. Mohammad Heidari

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The Academic Center for Education, Culture and Research, Qom Branch, Safashahr St, Jihad Daneshgahi Ally, Qom, Iran

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info.qm@acecr.ac.ir

**Web page address**<http://jd-qom.ac.ir/fa>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iranian academic center for education culture and research

**Proportion provided by this source**

100

**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**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

Hoda Fazaeli

**Position**

Researcher

**Latest degree**

Master

**Other areas of specialty/work**

Reproductive Biology

**Street address**

The Academic Center for Education, Culture and Research, Qom Branch, Shabnam St, Isar Sq, Imam Khomeini Town (Bonyad), Department of Stem Cell, Qom, Iran

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hodafazaely@yahoo.com

**Web page address**<https://www.rooyaivf.ir/fa/>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

Mohsen Sheykhhasan

**Position**

Researcher

**Latest degree**

Master

**Other areas of specialty/work**

Medical Biotechnology

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**Person responsible for updating data****Contact****Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

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**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Biology

**Street address**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**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**

The final report of the data will be given to the research deputy of Qom ACECR

**When the data will become available and for how long**

6 months after publishing the results

**To whom data/document is available**

General surgeon and specialist fistula surgeon

**Under which criteria data/document could be used**

All researchers are allowed to receive work protocols and data in accordance with the principles of professional ethics

**From where data/document is obtainable**

Contact the author by email at  
mohsen.sh2009@gmail.com

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

Contacting the author's email  
(mohsen.sh2009@gmail.com) takes about ten days.

**Comments**