Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Sheykhhasan

Name of organization / entity

Country

Iran (Islamic Republic of)

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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

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
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Web page address
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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
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

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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