Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Platelet-Rich Plasma Injection in the Treatment of Acute Anal Fissure

Protocol summary

Study aim
Determining the effect of local injection of platelet-enriched plasma in the treatment of patients with acute anal fissure

Design
The clinical trial has a control group, parallel, randomized to 56 patients. Randomization is done using the blocking method (Explained in the randomization section).

Settings and conduct
Standard anal fissure treatment includes stool softeners, topical diltiazem, and topical lidocaine, and in addition to standard treatment, the intervention group will receive two local injections of autologous platelet-enriched plasma at the site of anal fissure with a 1-week interval. Follow-up of patients will be one week and one month after the second injection.

Participants/Inclusion and exclusion criteria
Patients with acute anal fissure (with symptoms less than 6 weeks) who are diagnosed by a surgeon with a history and physical examination. Patients with chronic fissure, fissure in atypical or multiple locations, inflammatory bowel disease, cancer, history of trauma, tuberculosis, immunodeficiency, sexually transmitted diseases, history of anorectal surgery, current and recent pregnancies are excluded.

Intervention groups
Patients with acute anal fissure who receive a topical injection of platelet-enriched plasma in addition to standard fissure anal treatment, including stool softner, topical diltiazem, and topical lidocaine.

Main outcome variables
Patients' pain is assessed with the VAS questionnaire. The surgeon will also evaluate the patient's defecation problems, constipation, bleeding, itching, and sores.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220220054071N1**
Registration date: **2022-03-06, 1400/12/15**
Registration timing: **prospective**

Last update: **2022-03-06, 1400/12/15**
Update count: **0**

Registration date
2022-03-06, 1400/12/15

Registrant information

Name
Amir Zamani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 5102 5000

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amir.zamani.66@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2022-10-12, 1401/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Platelet-Rich Plasma Injection in the Treatment of Acute Anal Fissure

Public title

Platelet-Rich Plasma Injection in acute anal fissure treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with acute anal fissure (clinical presentation in less than 6 weeks)

Exclusion criteria:

Patients with anal fissures occurring in more than 6 weeks Patients with anal fissures in atypical locations Patients with multiple fissures Patients with inflammatory bowel disease cancer patients patients with sexually transmitted diseases history of anorectal surgery patients with immunodeficiency pregnancy patients with tuberculosis

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done by dividing included patients into some blocks of size 2n(2,4,6,8 and...), then randomizing patients in each block will be done such that n patients are allocated to the experimental group and control group. then we will choose the blocks randomly. This method ensures equal treatment allocation within each block when the complete block is used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Iran, Tehran Velenjak St. , Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

198353-5511

Approval date

2022-02-09, 1400/11/20

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.729

Health conditions studied

1

Description of health condition studied

Anal fissure

ICD-10 code

K60

ICD-10 code description

Fissure and fistula of anal and rectal regions

Primary outcomes

1

Description

patient complaint about anal fissure

Timepoint

one week and one month after the second injection of PRP

Method of measurement

pain, bleeding during defecation, itching and the appearance of the wound from the surgeon's point of view

2

Description

patient pain

Timepoint

one week and one month after the second injection of PRP

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: : A group of patients with acute anal fissures who, in addition to the classic treatment, receive PRP as an injection at the base of the wound. In order to prepare PRP or platelet-rich plasma, the patient is first given intravenous blood samples and tubes containing anticoagulants, citric acid, dextrose and thrombin are filled. The tubes are centrifuged at 3000 rpm for 8 minutes and platelet-rich plasma is collected using angiocatheter and platelet separation from the buffer coat. Then between 3 and 5 cc of PRP is injected into the

syringe. 0.1 cc is injected at a distance of half a centimeter of healthy tissue into the wound each time. Classical therapy includes topical nitroglycerin, nifedipine, and lidocaine, which are routinely used for this purpose. The centrifuge used is an 8-branch model of 4000 rpm made by Rooyagen Company. Raw materials are prepared from the same company.

Category

Treatment - Other

2

Description

Control group: Patients with acute anal fissure receiving standard anal fissure treatment including fecal emollients, topical deltiazem, and topical lidocaine.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Amir Zamani

Street address

Iran, Tehran, Makhsoos street, Loghman Hakim Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Bldg No.2, Shahid Beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leila Vatuizade

Position

Genereal surgery resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Participants' data file, study protocol, statistical analysis map, informed consent form and clinical study report will all be fully shareable after disclosing personal information.
When the data will become available and for how long
6 months after printing the results
To whom data/document is available
The information will be available to anyone who requests access
Under which criteria data/document could be used
Data are provided to study the study process or use in systematic review studies and meta-analysis.
From where data/document is obtainable
correspondence: Amir Zamani, Email: amir.zamani.66@gmail.com Address: School of Medicine ,Shahid Beheshti University of Medical Sciences, Yemen St., Shahid Chamran Highway, Tehran ,Iran Postal Code: 1985717443
What processes are involved for a request to access data/document
After sending the request for access to information and determining the type of requested information to the email of the person in charge of correspondence, she will prepare the requested information and send it to the applicant within one month.
Comments