

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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)

Phone

+98 21 5102 5000

Email address

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 diltiazem, 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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loghman.hospital@sbmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

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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7th Floor, Bldg No.2 Shahid Beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Zamani

Position

Assistant professor

Latest degree

Specialist

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Latest degree

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Other areas of specialty/work

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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