

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluating the effect of autologous platelet-rich plasma on the improvement of therapeutic effectiveness of the classic approach to anal

#### Protocol summary

##### Study aim

Evaluation of the effect of using autologous platelet-rich plasma (Autologous PRP) in improving the therapeutic effect of the classical approach to anal fissure

##### Design

The clinical trial has a control group, parallel, randomized to 60 patients. Randomization is done using the blocking method

##### Settings and conduct

First, for patients who have been diagnosed with acute or chronic anal fissure, the research plan is explained and after signing the informed consent, they enter to the study. Demographic information, history and systematic physical examination are obtained from patients. Then patients are divided into two groups of intervention and control. Patients in the intervention group, while receiving classical treatment (nitroglycerin / nifedipine and topical lidocaine), refer to Shahid Modarres Hospital for injection of platelet-rich plasma twice in two weeks. For this purpose, blood samples are taken from patients and PRP is obtained from the blood received. The patient is then transferred to an outpatient operating room and under local anesthesia in a dorsal lithotomy position at the base of the wound PRP injection. The same procedure is repeated two weeks later, during which time the patient is followed up by telephone every 7 days. Two weeks after last injection, the patient goes to the surgery clinic of the Hospital for examination.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with anal fisher Exclusion criteria: diabetes, immunodeficiency

##### Intervention groups

A group of patients with anal fissure who, in addition to the classic treatment, receive PRP as an injection at the base of the wound.

##### Main outcome variables

Change in pain, bleeding, itching and burning based on the patient's self-expression Wound evaluation based on the surgeon's opinion during the examination.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201225049826N1**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

##### Registration date

2021-12-01, 1400/09/10

##### Registrant information

##### Name

Hamed Ebrahimibagha

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 9770

##### Email address

h.ebrahimi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-22, 1400/04/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effect of autologous platelet-rich plasma on the improvement of therapeutic effectiveness of the classic approach to anal

**Public title**

Impact of platelet-rich plasma on anal fissure

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients diagnosed with anal fissure Consent for entering to the study

**Exclusion criteria:**

Patients with inflammatory bowel disease or other conditions which can cause secondary anal fissure  
Patients with diabetes  
Patients with immune deficiency

**Age**

From **20 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, in order to balance the number of samples in each group, the blocking method (with unequal sizes of 2, 4 and 6) will be used for random allocation. In this method, first the list of all permutations related to the desired block sizes is determined and then it is randomly selected according to the number of samples of permutations. Given that preparing a list of all permutations will take time. Random generation and selection of permutations is done using programming or reputable sites to generate a block randomization list.

**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**

2021-06-28, 1400/04/07

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1400.190

**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**

Incidence of wound healing

**Timepoint**

Initiation of the study, two weeks after injection, four weeks after injection, one month after the first injection

**Method of measurement**

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

**Secondary outcomes**

empty

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

Intervention group: A group of patients with 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 1600 rpm for 12 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 Alminogster Company. Raw materials are prepared from Noavaran Salamat Arjang

Company to prepare PRP.

**Category**

Treatment - Other

**2****Description**

Control group: A group of patients with anal fissure who actually receive only classical treatment and are examined for comparison with the intervention group. Classical therapy includes topical nitroglycerin, nifedipine, and lidocaine, which are routinely used for this purpose.

**Category**

Treatment - Drugs

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

Modarres hospital

**Full name of responsible person**

Adel Zeinalpour

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Saadat Abad St.,Yadegare Imam Highway, Tehran, Iran

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pr\_modaress@sbmu.ac.ir

**Web page address**

<http://modarres.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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**Email**

Intl\_office@sbmu.ac.ir

**Web page address**

<http://research.sbmu.ac.ir/>

**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**

Hamed Ebrahimibagha

**Position**

medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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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**

Adel Zeinalpour

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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adel.zeinalpour@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hamed Ebrahimibagha

**Position**

Medical Intern- Researcher

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**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**

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: Hamed Ebrahimibagha, Email: h.ebrahimi@sbmu.ac.ir 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 specifying the type of requested information to the email of the person in charge of correspondence, they will prepare the requested information and send it to the applicant.

**Comments**