Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1998734383

Phone

+98 21 2207 4087

Fax

+98 21 2207 4101

Email

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.

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

Fax

+98 21 2243 3455

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

Street address

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

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

Email

h.ebrahimi@sbmu.ac.ir

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

Street address

Shahid Beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

Email

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

7th Floor, Bldg No.2 Shahid Beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran. Post Code: 19839-63113

City

Tehran

Province

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19839-63113

Phone

+98 21 2243 9770

Fax

Email

h.ebrahimi@sbmu.ac.ir

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