

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of blind anal fistula treatment (BAFT) for anal fistula treatment

Protocol summary

Study aim

Evaluation of blind anal fistula treatment (BAFT) for anal fistula treatment

Design

Randomized clinical trial with control group, randomized (six-block), single-blind, with parallel groups and phase 2-3

Settings and conduct

In this randomized clinical trial study, 50 patients will be divided into two groups and after division, the relevant surgical procedure will be performed for them; For the intervention group, surgery will be performed by BAFT method and the control group will perform surgery by routine method and finally their recovery will be compared. The person analyzing the results will be unaware of the grouping of patients and will remain blind during the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria are candidates for pre-anal fistula surgery and Exclusion criteria: History of diabetes, patients with coagulation problems and patients with inflammatory bowel disease.

Intervention groups

This study will be a randomized, single-blind clinical trial in Imam Reza Hospital (Tabriz University of Medical Sciences) with the participation of 50 patients. Patients will be randomly divided into two groups, the surgical intervention group will perform BAFT method and the control group will perform routine surgery. Finally, patients' pain and recovery status will be assessed.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N29**

Registration date: **2022-04-28, 1401/02/08**

Registration timing: **prospective**

Last update: **2022-04-28, 1401/02/08**

Update count: **0**

Registration date

2022-04-28, 1401/02/08

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of blind anal fistula treatment (BAFT) for anal fistula treatment

Public title

Blind anal fistula treatment (BAFT) for anal fistula treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for preanal fistula surgery

Exclusion criteria:

History of diabetes Patients with coagulation problems

Patients with inflammatory bowel disease

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block random division method (4 blocks) is used. One of the study partners, for whom blindness has not been performed, names the treatment with the letters A and B. The researcher then distributes packages A and B among the patients referred to participate in the study by block random division method (4). Then, from the created blocks, enough blocks are randomly selected to reach the required sample size.

How to create a random sequence using randomization was simple. To make a random sequence, we give possible blocks (6 blocks) from one to 6 numbers.

Depending on the sample size, any number of 4 blocks that are needed will be used. Select the number of blocks from the table of random numbers and based on these numbers, the sequence of blocks in each group will be determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the data analyzer will be unaware of the grouping of patients and will only analyze the data; Therefore, the person analyzing the results will be blind during the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

IR.TBZMED.REC.1400.1151

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.29

ICD-10 code description

Other chronic pain

Primary outcomes

1

Description

Pain

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Anal fistula healing

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: A total of 25 patients will be included in this group after random allocation. Patients will be hospitalized and then transferred to the operating room. The BAFT method will then be used for their surgery. Before surgery and two weeks after surgery, the severity of pain and the extent of anal fistula healing in patients

will be evaluated.

Category

Treatment - Surgery

2**Description**

Control group: A total of 25 patients will be included in this group after random allocation. Patients will be hospitalized and then transferred to the operating room. Then the routine method of anal fistula surgery will be used for their surgery. Before surgery and two weeks after surgery, the severity of pain and the extent of anal fistula healing in patients will be evaluated.

Category

Treatment - Surgery

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

Imam Reza Hospital

Full name of responsible person

Ramin Azhogh

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

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Full name of responsible person

Parviz Shahabi

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Shahabi_p@hotmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

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

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Person responsible for updating data**Contact****Name of organization / entity**

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Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available