

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation clinical consequence of fistulectomy with or with out immediate sphincteroplasty in the treatment of anal fistula

Protocol summary

Study aim

Comparison of fistulectomy surgery with sphincterolasty in the treatment of anal fistula

Design

In order to randomly allocate the samples to two groups, a simple random method will be used, which is determined by the qualified patient's referral based on the entry and exit criteria, and by using a table of random numbers and selecting even or odd numbers for the allocation of the patient to the relevant group. The study is blinded from the point of view of the patients and the evaluator, and the patient and the evaluator are not aware of the possible outcomes and complications after the operation, but the surgeon is.

Settings and conduct

The intended study will be a single-blind randomized clinical trial on patients referred to Imam Khomeini Hospital in Sari during the years 1401-1402.

Participants/Inclusion and exclusion criteria

1. Patients with anal fistula referred to Imam Hospital in the age range of 15-80 years 2. Consent to participate in the study

Intervention groups

Patients with anal fistula referred to Imam Hospital in the age range of 15-80 years

Main outcome variables

Gas and stool incontinence Recurrence rate Duration of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221211056784N1**

Registration date: **2022-12-26, 1401/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-26, 1401/10/05**

Update count: **0**

Registration date

2022-12-26, 1401/10/05

Registrant information

Name

Akram Kalani sarokolaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4204 1154

Email address

akram.kalani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-12, 1401/09/21

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation clinical consequence of fistulectomy with or with out immediate sphincteroplasty in the treatment of anal fistula

Public title

Fistulectomy with or with out primery repair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with anal fistula in 15_80 age
Exclusion criteria:
Pregnancy History of anal surgery Coagulation disorder

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

By calculating the sample size, taking into account a certain number of patients, they will be divided into two equal groups, the number of measurement times is 4 times. The sample collection is based on the goal and based on the entry and exit criteria. In order to randomly allocate the samples to two groups, a simple random method will be used, which is determined by the qualified patient's referral based on the entry and exit criteria, and by using a table of random numbers and selecting even or odd numbers for the allocation of the patient to the relevant group. The study is blinded from the point of view of the patients and the evaluator, and the patient and the evaluator are not aware of the possible outcomes and complications after the operation, but the surgeon knows.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to randomly allocate the samples to two groups, a simple random method will be used, which is determined by the qualified patient's referral based on the entry and exit criteria, and by using a table of random numbers and selecting even or odd numbers for the allocation of the patient to the relevant group. The study is blinded from the point of view of the patients and the evaluator, and the patient and the evaluator are not aware of the possible outcomes and complications after the operation, but the surgeon is.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sari University of Medical Sciences

Street address

Imam khomeini hospital., Amir mazandarani Ave
.,Sari., Iran

City

Sari

Province

Mazandaran

Postal code

4764647343

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1401.002

Health conditions studied

1

Description of health condition studied

Anal fistula

ICD-10 code

K60.3

ICD-10 code description

Anal fistula

Primary outcomes

1

Description

Recurrence rate

Timepoint

One week, two weeks, 1, 3, 6 and 12 months after the surgery, the patients are re-examined and they are studied in recurrence rate

Method of measurement

through a questionnaire

2

Description

Gas and stool incontinence

Timepoint

One week, two weeks, 1, 3, 6 and 12 months after the surgery

Method of measurement

through a questionnaire

3

Description

Postoperative satisfaction rate

Timepoint

One week, two weeks, 1, 3, 6 and 12 months after the surgery

Method of measurement

through a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: primary sphincteroplasty after fistulectomy in this group after fistulectomy is performed simultaneously in the same primary tissue repair operation with thread. And the results of this type of tissue repair, including the rate of recurrence and incontinence, are compared with the control group

Category

Treatment - Surgery

2

Description

Control group: fistulectomy without sphincteroplasty. In this group, after sphincterotomy, the tissue defect is repaired in a secondary way and over time, and there is no intervention after sphincterotomy for repair.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari

Full name of responsible person

akram kalani

Street address

Imam khomeini hospital., Amir mazandarani Ave
.,Sari., Iran

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Email

neda_kalani22@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran university of medical science

Full name of responsible person

Dr. Pedram Ebrahim Nehad

Street address

Imam khomeini hospital., Amir mazandarani Ave

.,Sari., Iran

City

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Mazandaran

Postal code

4734347646

Phone

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Email

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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

Mazandaran university of medical science

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

Mazandaran University of Medical Sciences

Full name of responsible person

Akram kalani

Position

General surgery resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Imam khomeini hospital., Amir mazandarani Ave
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Person responsible for scientific inquiries

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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