

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 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

#### City

Sari

#### Province

Mazandaran

#### Postal code

۴۷۳۴۳۴۷۶۴۶

#### Phone

+98 11 4204 1154

#### 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

Sari

#### Province

Mazandaran

#### Postal code

4734347646

#### Phone

+98 11 4204 1154

#### Email

neda\_kalani22@yahoo.com

#### 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  
.,Sari., Iran

#### City

Ghaemshahr

#### Province

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#### Postal code

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#### Phone

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#### Email

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## Person responsible for scientific inquiries

### Contact

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Mazandaran University of Medical Sciences

**Full name of responsible person**

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**Person responsible for updating data**

**Contact**

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Mazandaran University of Medical Sciences

**Full name of responsible person**

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**Latest degree**

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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