

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative study of the rate of recovery and postoperative complications of two mucopexy surgical methods with and without Doppler Guided Hemorrhoidal Artery Ligation (DG-HAL) in patients with grade 3 and 4 hemorrhoids

#### Protocol summary

##### Study aim

We compare the rate of recovery and postoperative complications in patients with grade 3 and 4 hemorrhoids in two mucopexy surgical methods with and without Doppler Guided Hemorrhoidal Artery Ligation(DG-HAL).

##### Design

This is a Randomized Clinical Trial study. The intervention group includes patients undergoing mucopexy with DG-HAL and the control group are patients undergoing mucopexy without DG-HAL. Sample size includes 36 patients, 18 in each parallel group. Patients are divided into two groups of intervention and control by randomization of allocating 5-digit special code to each individual. The study is single-blinded and only patients (participants) are not aware of the mucopexy surgical methods. The trial phase is 2-3.

##### Settings and conduct

Study Setting: General Surgery, Colorectal Surgery,  
Study Location: Firoozgar Hospital, Tehran, Study  
Method: Interventional (clinical trial), Single-Blinded: only the patients (participants) are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with diagnosis of Grade 3 and 4 hemorrhoids. Exclusion Criteria: Patients with diagnosis of Grade 1 and 2 hemorrhoids, Patients with underlying disease such as diabetes and hypertension, Patients with a history of hemorrhoidal surgery, Patients with a history of rectal surgery.

##### Intervention groups

Intervention group includes patients undergoing mucopexy operation with DG-HAL, The control group includes patients undergoing mucopexy operation without DG-HAL.

##### Main outcome variables

Recovery rate; postoperative complications.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190927044897N1**

Registration date: **2019-10-29, 1398/08/07**

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

Last update: **2019-10-29, 1398/08/07**

Update count: **0**

##### Registration date

2019-10-29, 1398/08/07

##### Registrant information

##### Name

Sara Sohrabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8214 1000

##### Email address

sohrabi.s@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2021-04-19, 1400/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparative study of the rate of recovery and postoperative complications of two mucopexy surgical methods with and without Doppler Guided Hemorrhoidal Artery Ligation (DG-HAL) in patients with grade 3 and 4 hemorrhoids

### Public title

The effect of mucopexy surgical method on the incidence of postoperative complications.

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients referred to Surgery Clinic of Firoozgar Hospital for diagnosis of grade 3 and 4 hemorrhoids.

#### Exclusion criteria:

Patients with diagnosis of grade 1 and 2 hemorrhoids  
Patients with underlying disease such as diabetes and hypertension  
Patients with a history of hemorrhoidal surgery  
Patients with a history of rectal surgery

### Age

No age limit

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Participant

### Sample size

Target sample size: 36

### Randomization (investigator's opinion)

Randomized

### Randomization description

Method of randomization in this study is Simple and unit of randomization is individual. No stratified randomization is used. Sealed envelopes are used as the tool in randomization. The random sequence is built by envelopes shuffling. In allocation concealment we consider a 5-digit code for each envelope and if the third number is even the patient is in case group. If the third number is odd the patient is in control group.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

All of the participants are aware of their participation in this study and have announced their consent forms. Also, this study has the permission from ethical committee of university. the study is single-blinded, and only the participants are unaware of which of the two mucopexy surgical methods with or without DG-HAL used to treat grade 3 and 4 hemorrhoids. Also, a checklist is provided for each patient, including name, age, sex, height, weight, BMI and demographic characteristics, as well as hemorrhoid grade. These checklists with surgical procedure name coded (mucopexy with DG-HAL) as even third digit in 5-digit code and (mucopexy without DG-HAL) as odd third digit in 5-digit code randomly given to the patients before their operation.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

Shahid Hemmat Highway, Tehran, Tehran Province

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2019-07-23, 1398/05/01

#### Ethics committee reference number

IR.IUMS.FMD.REC.1398.167

## Health conditions studied

### 1

#### Description of health condition studied

Grade 3 and 4 Hemorrhoids, Doppler Guided Hemorrhoidal Artery Ligation, Mucopexy with DG-HAL, Mucopexy without DG-HAL, General Surgery, Colorectal Surgery, Anorectal Diseases

#### ICD-10 code

K64

#### ICD-10 code description

Hemorrhoids and perianal venous thrombosis

### 2

#### Description of health condition studied

Grade 3 and 4 Hemorrhoids, Mucopexy with DG-HAL, Mucopexy without DG-HAL, General Surgery, Colorectal Surgery, Anorectal Diseases

#### ICD-10 code

K64.3

#### ICD-10 code description

Fourth degree hemorrhoids

## Primary outcomes

### 1

#### Description

The incidence percentage of postoperative complications

of mucopexy with and without DG-HAL in patients with grade 3 and 4 hemorrhoids

#### **Timepoint**

One, three and six months after operation

#### **Method of measurement**

According to checklists and evidence of patients' history and physical examination in follow-up visits for presence or absence of pain, signs of infection, bleeding, gas incontinence, stool incontinence, anal stenosis, fistula, prolapse and hemorrhoid recurrence

## **Secondary outcomes**

### 1

#### **Description**

The rate of recovery

#### **Timepoint**

One, three and six months after operation

#### **Method of measurement**

Checklists and evidence of patients' history and physical examination in follow-up visits for presence or absence of pain, signs of infection, bleeding, gas incontinence, stool incontinence, anal stenosis, fistula, prolapse, and hemorrhoid recurrence

## **Intervention groups**

### 1

#### **Description**

Intervention group: includes patients undergoing mucopexy with DG-HAL. These patients have grade 3 and 4 hemorrhoids requiring surgical intervention. DG-HAL mucopexy surgery is performed by blocking hemorrhagic artery and hemorrhoid repair using Doppler device during surgery.

#### **Category**

Treatment - Surgery

### 2

#### **Description**

Control group: includes patients undergoing mucopexy without DG-HAL. These patients have grade 3 and 4 hemorrhoids requiring surgical intervention. mucopexy surgery without DG-HAL is performed without the use of a Doppler device during hemorrhoid repair.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Firoozgar Hospital

##### **Full name of responsible person**

Sara Sohrabi

##### **Street address**

Firoozgar Hospital, Beh Afarin Avenue, Karim Khan

Zand street, Valiasr Square, Tehran

#### **City**

Tehran

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#### **Postal code**

1593747811

#### **Phone**

+98 21 8214 1600

#### **Email**

h\_firoozgar@yahoo.com

#### **Web page address**

<http://firoozgar.iums.ac.ir/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Seyyed Abbas Motevalian

##### **Street address**

Vice Chancellor for Research and Technology, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

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research@iums.ac.ir

##### **Web page address**

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

No

#### **Title of funding source**

Iran University of Medical Sciences

#### **Proportion provided by this source**

50

#### **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

### 2

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Mahdi AlemRajabi

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Firoozgar Hospital, Beh Afarin Avenue., Karim Khan Zand street., Valiasr Square, Tehran

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http://firoozgar.iums.ac.ir/

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

No

**Title of funding source**

Firoozgar Clinical Research Development Center(FCRDC), Firoozgar Hospital

**Proportion provided by this source**

50

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Sara Sohrabi

**Position**

Doctor of Medicine (Intern)

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

Faculty of Medicine, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

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

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**Full name of responsible person**

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**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

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

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

Doctor of Medicine Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**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**

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

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

All data can potentially be shared after making people unrecognizable.

**When the data will become available and for how long**

starting of accessibility will be 6 months after publication

**To whom data/document is available**

only available for people working in academic institutions

**Under which criteria data/document could be used**

- researchers - people working in academic institutions - data could not be used in other studies. - data is available for elucidating the results of this study.

**From where data/document is obtainable**

contact responsible person: dr. Sara Sohrabi, academic e-mail address: sohrabi.s@tak.iuums.ac.ir , address: Firoozgar Hospital, Beh Afarin Ave., Valiasr Square, Tehran second responsible person: dr. Mahdi AlemRajabi , Assistant professor, e-mail address: mahdialemlrajabi@gmail.com

**What processes are involved for a request to access data/document**

researcher information including name, address, telephone number and e-mail address - researcher CV/resume - Sending a request letter to responsible person for accessing data - Approval letter from academic institution

**Comments**