Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 mucopoxy 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

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Iran (Islamic Republic of)

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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

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

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Sponsors / Funding sources

1

Sponsor

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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

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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
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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.iums.ac.ir , address: Firoozgar Hospital, Beh Afarin Ave., Valiasr Square, Tehran second responsible person: dr. Mahdi AlemRajabi , Assistant professor, e-mail addres: mahdialemrajabi@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