

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Comparative study of the effectiveness of two methods of drug therapy and band ligating in controlling bleeding and treatment in patients with hemorrhoids of grade 2 and 3

#### Protocol summary

##### Study aim

1. Determining the frequency distribution of hemorrhage in patients undergoing drug treatment, ten days after starting treatment 2. Determining the frequency distribution of the necessary turns of the ligation band to stop the bleeding 3. Determining the frequency distribution of the necessary turns of the ligation band to remove the hemorrhoid (eradication) 4. Comparison of the frequency distribution of hemorrhage in patients treated with ligation band and drug treatment 5. Comparison of frequency distribution of recurrence in one-year follow-up period in patients undergoing ligation and drug treatment

##### Design

Randomized, parallel group trial without blinding. Randomization was done with a randomization random numbers software.

##### Settings and conduct

The study is performed in the clinics of Khorshid and AlZahra hospitals. The control group receives drug treatment and the intervention group undergoes ligation. The drug treatment group is re-visited ten days after the start of treatment. The ligation band group is visited every month to a year and, if necessary, is re-ligated bandage until the hemorrhoid warts are completely removed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: People with grade 2 and 3 hemorrhoids and rectal bleeding without other anorectal problems  
Exclusion criteria: 1. Conscious dissatisfaction 2. Coagulation problems 3. Immune deficiency 4. Cirrhosis of the liver 5. portal hypertension

##### Intervention groups

Sixty patients with a diagnosis of grade 2 or 3 internal hemorrhoids are randomly divided into two groups. Half of the patients are treated with antihemorrhoid ointment. The second group of patients are treated with ligation

band method.

##### Main outcome variables

Type of treatment, independent, nominal; recurrence, dependent, nominal; bleeding, dependent, nominal; age, underlying, continuous; sex, underlying, nominal; response time, dependent, continuous

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210630051748N1**

Registration date: **2021-07-13, 1400/04/22**

Registration timing: **prospective**

Last update: **2021-07-13, 1400/04/22**

Update count: **0**

##### Registration date

2021-07-13, 1400/04/22

##### Registrant information

##### Name

azam teimouri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 3071

##### Email address

a\_teimouri@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-27, 1400/05/05

##### Expected recruitment end date

2021-08-23, 1400/06/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
Comparative study of the effectiveness of two methods of drug therapy and band ligating in controlling bleeding and treatment in patients with hemorrhoids of grade 2 and 3

**Public title**  
Comparison of the effectiveness of drug treatment and elastic band therapy in the treatment of hemorrhoids

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

People with grade 2 and 3 hemorrhoids and with anal bleeding who do not have another anorectal problem

**Exclusion criteria:**

concomitant external hemorrhoids coagulation disorder immunodeficiency liver cirrhosis taking anticoagulants drugs

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation of double blocks

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Isfahan university of medical science ethical committee

**Street address**

Hezar jarib

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2021-06-29, 1400/04/08

**Ethics committee reference number**

IR.MUI.MED.REC.1400.239

**Health conditions studied**

1

**Description of health condition studied**

Hemorrhoid

**ICD-10 code**

K64

**ICD-10 code description**

Hemorrhoids and perianal venous thrombosis

**Primary outcomes**

1

**Description**

Recurrence of hemorrhoid after band ligation or medical treatment

**Timepoint**

Four weeks after intervention

**Method of measurement**

Physical examination

2

**Description**

Bleeding

**Timepoint**

Four weeks after intervention

**Method of measurement**

Measuring bleeding volume by cc

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Band ligation; The patients supposed to be treated with band ligation are required to lie in the knee chest or lateral position. First, the anus is lubricated with Lidocaine gel, and then the anoscope is inserted into the anus, and with a hemorrhoidectomy device connected to a suction tube, one or two elastic bands are used to ligate the band. Then, the patient is given the necessary explanations for not using suppositories and

ointments during this period. The patient is then recommended to return for re-examination one month after hemorrhoidectomy and, if necessary, re-ligation. The patient then visits every month for complete removal of the hemorrhoid patches and one year after complete recovery the patient returns for re-evaluation to check for recurrence.

#### Category

Treatment - Other

## 2

#### Description

Control group: Medical treatment; These patients are treated with anti-hemorrhoid ointment. Patients are then told to see their doctor again after a month. These referrals are repeated every month for a year.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Isfahan Alzahra Hospital

**Full name of responsible person**

Azam Teimouri

**Street address**

Sofe street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

alzahra@mui.ac.ir

### 2

#### Recruitment center

**Name of recruitment center**

Isfahan Khorshid Hospital

**Full name of responsible person**

Azam teimouri

**Street address**

Ostandari street

**City**

Isfahan

**Province**

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**Postal code**

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**Phone**

+98 31 3222 2127

**Email**

dean@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mojgan Mortazavi

**Street address**

Hezar jarib

**City**

Isfahan

**Province**

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**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

dean@med.mui.ac.ir

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Azam Teimouri

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Hezar jarib

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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**Postal code**

8174673461

**Phone**

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**Email**

a\_teimouri@med.mui.ac.ir

## 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

Excel file of all variables without mentioning name and address

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

From Farvardin1401 for one year

**To whom data/document is available**

Physicians and researchers

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

In order to conduct more clinical studies and to treat patients better

**From where data/document is obtainable**

Dr. Azam Teimouri

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

Sending an email to the project executor, receiving a response email and specifying the reason for the need for data, reviewing the request, sending the data

**Comments**