

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### A comparison of open hemorrhoidectomy vs closed in patients admitted in Imam Khomeini hospital, Sari, Iran 2008-2009

#### Protocol summary

##### Summary

The aim of this randomized clinical trial is to compare between two surgical methods for hemorrhoidectomy those are named Milligan -morgan (Open=group A) and Ferguson (Close=group B) regarding postoperative signs, symptoms and long term result in Imam Khomeini hospital of Sari, Iran. A total of 100 patients with third or fourth degree hemorrhoid hemorrhoidectomy and meeting eligibility criteria are randomly allocated into two groups. In 50 patients milligan -morgan(open) method is used; in this method after resection the hemorrhoid and ligation the pedicle wounds are not closed and in other 50 patient Ferguson (close ) method is used; in this method after hemorrhoidectomy wounds are closed. Details of operations, post operative complications and length of postoperative stay are recorded. Pain is assessed from a Visual Analogue Scale and by registration of postoperative analgesic medication. Follow -up is done at hours 6 and 24 and days 14 and 28. Wound healing duration, postoperative bleeding, wound hematoma, abscess, fistula formation and anal stricture are followed by visits or telephone interview by surgeon once a week for one month and once a month for six months and result are compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201202041786N2**  
Registration date: **2012-02-27, 1390/12/08**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-02-27, 1390/12/08

#### Registrant information

##### Name

Nasrin Rahmani

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1226 1700

##### Email address

nrahmani@mazums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Mazandaran University of Medical Sciences

#### Expected recruitment start date

2010-09-23, 1389/07/01

#### Expected recruitment end date

2011-09-23, 1390/07/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparison of open hemorrhoidectomy vs closed in patients admitted in Imam Khomeini hospital, Sari, Iran 2008-2009

#### Public title

Comparison between two surgical methods for hemorrhoid treatment

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criterion: all patients with third and fourth degree hemorrhoid suitable for hemorrhoidectomy  
Exclusion criteria: patients with other anorectal diseases like fissure

or fistula; patients who have contraindication for anesthesia; every patient with wound healing problem and high risk for infection like diabetes mellitus.

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: **100**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **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**

Mazandaran university of medical sciences

##### **Street address**

Moallem square, Building NO 2

##### **City**

Sari

##### **Postal code**

#### **Approval date**

2010-09-08, 1389/06/17

#### **Ethics committee reference number**

89-67

## **Health conditions studied**

### 1

#### **Description of health condition studied**

hemorrhoid

#### **ICD-10 code**

I84.8, I84.

#### **ICD-10 code description**

hemorrhoids with complication\_hemorrhoids without complication

## **Primary outcomes**

### 1

#### **Description**

Pain severity

#### **Timepoint**

Hours 6 and 24 and days 14 and 28 postoperative

#### **Method of measurement**

Visual Analogus Scale

### 2

#### **Description**

Bleeding and hematoma

#### **Timepoint**

Every week for one month and every month for 6 months

#### **Method of measurement**

Physical examination

### 3

#### **Description**

Post operative hospital stay

#### **Timepoint**

Hospital stay

#### **Method of measurement**

Medical file

### 4

#### **Description**

Duration of operation

#### **Timepoint**

Record in the operative room at the time of operation

#### **Method of measurement**

Medical file

## **Secondary outcomes**

### 1

#### **Description**

Abcess and fistula formation

#### **Timepoint**

Every week for one month and every month for 6 months

#### **Method of measurement**

Visit or telephone interview

### 2

#### **Description**

Anal stricture

#### **Timepoint**

Month sixth

#### **Method of measurement**

visit

## **Intervention groups**

### 1

#### **Description**

Closing the wound after resection the hemorrhoids and ligation the vascular pedicle (Ferguson method)

**Category**

Treatment - Surgery

**2****Description**

Wounds are not closed after hemorrhoid resection and ligator of pedicle(Milligan-Morgan)

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini general Hospital

**Full name of responsible person**

Dr Nasrin Rahmani Boeeni

**Street address**

Amir Mazandarani Bulvar,Emam Khomaini Hospital

**City**

Sari

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Ahmad Ali Enayati

**Street address**

Moallem Square-Bulding NO 2

**City**

Sari

**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 Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Surgery ward- Imam Khomeini Hospital

**Full name of responsible person**

Dr Nasrin Rahmani Boeeni

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Amia Mazandarani Bulv.

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**Postal code****Phone**

+98 15 1226 3537

**Fax****Email**

nrahmani@mazums.ac.ir; drrahmani124@gmail.com

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Nasrin Rahmani Boeeni

**Position**

Assistant Professor, General Surgeon

**Other areas of specialty/work****Street address**

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

Imam Khomeini Hospital

**Full name of responsible person**

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**Position**

Assistant Professor

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**Web page address**

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*