

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparison the effects of topical Atorvastatine (2%) with placebo for post-hemorrhoidectomy pain relief and wound healing

#### Protocol summary

##### Summary

Hemorrhoids define as enlargement and distal displacement of the normal anal cushions which manifest by pain and rectal bleeding associated with bowel movement. Excision hemorrhoidectomy is the most effective treatment for hemorrhoids with lowest rate of recurrence compared to other modalities. A major drawback of hemorrhoidectomy is postoperative pain. The aim of the present study is to investigate the effects of topical atorvastatine in reduction of postoperative pain relief and wound healing. Type of study: A prospective, double-blind, randomized, placebo controlled trial. Inclusion criteria: All 18-65 years old patients who had hemorrhoidectomy surgery. Exclusion criteria: Individuals who show hypersensitivity to the product or improve symptoms of myopathy, the patients with renal failure and those with increased ulcer size after using the product. Intervention 1: Topical atorvastatine (2%), twice daily for two months. Intervention 2: Placebo (topically), twice daily for two months. Outcomes: 1) Pain. Methods of measurement: Visual Analog Scale (VAS). 2) Itch. Method: D-5.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201404013014N8**

Registration date: **2014-10-12, 1393/07/20**

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

Last update:

Update count: **0**

##### Registration date

2014-10-12, 1393/07/20

##### Registrant information

##### Name

Shahram Ala

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1354 3083

##### Email address

sala@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mazandaran University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2014-07-23, 1393/05/01

##### Expected recruitment end date

2015-07-23, 1394/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effects of topical Atorvastatine (2%) with placebo for post-hemorrhoidectomy pain relief and wound healing

##### Public title

The effects of topical atorvastatine (2%) for post-hemorrhoidectomy pain relief and wound healing

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients who had hemorrhoidectomy surgery between 18-65 years old! Exclusion criteria: Patients with hypersensitivity to atorvastatine :

and those who develop myopathy, renal failure or ulcer size

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mazandaran University of Medical Sciences, Ethical Committee

##### Street address

Vice chancellor of research , Moalem square

##### City

Sari

##### Postal code

##### Approval date

2014-04-22, 1393/02/02

##### Ethics committee reference number

49870

## Health conditions studied

### 1

#### Description of health condition studied

Excisional hemorrhoidectomy

#### ICD-10 code

I84.5

#### ICD-10 code description

External haemorrhoids with other complications

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Each week for 2 weeks then each month for 2 month

#### Method of measurement

Visual Analog Scale(VAS)

## Secondary outcomes

### 1

#### Description

Itching

#### Timepoint

Once monthly for two month

#### Method of measurement

5D

## Intervention groups

### 1

#### Description

Intervention1: Topical atorvastatine (2%) BID for two weeks. each dose 1cm.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention 2: Placebo, BID for two weeks, each dose 1cm

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tooba special clinic

##### Full name of responsible person

Maliheh Hamidian

##### Street address

Tooba special clinic, Khazar street, Sari, Iran

##### City

Sari

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences, Vice chancellor for research

##### Full name of responsible person

Dr.Ahmad Enayati

**Street address**

Mazandaran University of Medical Sciences, Vice  
chancellor for research and technology, Moallem  
square, Sari, Mazandaran, Iran

**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, Vice  
chancellor for research

**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**

Mazandaran University of Medical Sciences, Vice  
chancellor for research

**Full name of responsible person**

Maliheh Hamidian

**Position**

Pharmacy student

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

Mazandaran University of Medical Sciences, Vice  
chancellor for research, Moallem square, Sari,  
Mazandaran, Iran

**City**

Sari

**Postal code****Phone**

+98 15 1311 0267

**Fax****Email**

maliheh.hamidian@yahoo.com

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

Clinical pharmacy specialist, Faculty of pharmacy, Sari

**Full name of responsible person**

Dr.Shahram Ala

**Position**

Associated professor of clinical pharmacy

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

Mazandaran University of Medical Sciences, Vice  
chancellor for research, Moallem square, Sari,  
Mazandaran, Iran

**City**

Sari

**Postal code****Phone**

+98 15 1354 3083

**Fax****Email**

sh204ala@yahoo.com

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

Mazandaran University of medical science

**Full name of responsible person**

Dr.Shahram Ala

**Position**

Associated professor of clinical pharmacy

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

Mazandaran University of Medical Sciences, Vice  
chancellor for research, Moallem square, Sari,  
Mazandaran, Ir

**City**

Sari

**Postal code****Phone**

+98 15 1354 3083

**Fax****Email**

sh204ala@yahoo.com

**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*