

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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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

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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

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Clinical pharmacy specialist, Faculty of pharmacy, Sari

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Position

Associated professor of clinical pharmacy

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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