Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 hemorroidectomy surgery between 18-65 years old؛ Exclusion criteria:Patients with hypersensivity to atorvastatine ؛

and those who develop myopathy, renal falier 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 Commitee

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

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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

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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