Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy of baclofen 5% cream in the reduction of postoperative pain after open hemorrhoidectomy: a prospective, double-Blind, randomized, placebo controlled clinical trial

Protocol summary

Summary

The object of this study is to evaluate the efficacy of topical baclofen in relieving post hemorrhoidectomy pain through a double-blind, randomized, placebo controlled trial. Sixty numbers of patients that have hemorrhoidectomy surgery are enrolled in the study. Individuals who show hypersensitivity to the product or taking oral baclofen are excluded from study. Patients will receive acetaminophen tablets as oral treatment and baclofen or placebo cream twice daily for one month. Pain intensity is measured by visual analog scale and recorded weekly after surgery. Side effects of product and the process of wounds healing during intervention are evaluated and recorded by the questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609163014N16**
Registration date: **2017-01-07, 1395/10/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-07, 1395/10/18

Registrant information

Name

Shahram Ala

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of baclofen 5% cream in the reduction of postoperative pain after open hemorrhoidectomy: a prospective, double-Blind, randomized, placebo controlled clinical trial

Public title

Efficacy of topical baclofen in the reduction of postoperative pain after hemorrhoidectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 20 and 70 years; candidate for hemorroidectomy surgery Exclusion criteria: Hypersensivity to baclofen; develop ulcer size; taking oral baclofen

Age

From **20 years** old to **70 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization is done using random number table. We give a code number to each patient that shows the group each patient is allocated to. The list of patients and their code numbers is kept secret until the end of the trial. In this way neither the patient nor the researchers know whether it is drug or placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University Medical Sciences
Street address
Moalem Sq.
City
Sari
Postal code
Approval date
2016-09-20, 1395/06/30
Ethics committee reference number
IR.Mazums.Rec.95-2624

Health conditions studied

1

Description of health condition studied
hemorrhoids
ICD-10 code
I84.4
ICD-10 code description
External haemorrhoids with other complications

Primary outcomes

1

Description
Pain intensity
Timepoint
7th, 14th, 21th, 28th day after surgery
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Side effects
Timepoint
7th, 14th, 21th, 28th day after surgery
Method of measurement
Questionnarie

Intervention groups

1

Description
Intervention: Baclofen 5% cream, twice daily until one month plus acetaminophen 325 mg tablets three times daily
Category
Treatment - Drugs

2

Description
Control: Placebo cream, without active ingredient, twice daily until one month plus acetaminophen 325 mg tablets three times daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital and educational center
Full name of responsible person
Dr. Shahram Ala
Street address
Payambar azam University Complex, Mazandaran University of Medical Sciences, Faculty of Pharmacy, Km 20 Khazar abad Road
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research, Mazandaran University of Medical Sciences

Full name of responsible person
Dr Ahmadali Enayatifar
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Payambar Azam University Complex, Mazandaran University of Medical Sciences, Km 20 Khazar Abad Road
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research, 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
Mazandaran University of Medical Science, Faculty of Pharmacy
Full name of responsible person
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Position
Clinical pharmacy specialist, Associated professor
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Person responsible for updating data

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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