

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison between topical phenytoin 1% and placebo locally to reduce postoperative pain and recovery time for patients with perianal fistula after fistulotomy

Protocol summary

Summary

The study is a randomized, double-blind, placebo-controlled, single-center. The study population: Exclusion criteria included: Long-term use of corticosteroids ;diabetes POORLY CONTROL;TB patients; people with Coron disease; people with underlying malignancy;patients who have had radiation; patients with a history cemothorapy less than 2 weeks; allergy to phenytoin. Inclusion criteria: all patients with anal fistula. Inclusion criteria: all patients with anal fistula. the total sample size are 44 patients. intervention: application of topical cream phenytoin 1% on wound healing after anal fistulectomy. after surgery primary outcome: accelerate healing, reduce pain,the Recurrence,Anal itching, fecal and gas continency

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041314483N4**

Registration date: **2016-03-21, 1395/01/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-21, 1395/01/02

Registrant information

Name

Mina Alvandipour

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1225 6329

Email address

malvandipour@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences and Health Services

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2016-03-21, 1395/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between topical phenytoin 1% and placebo locally to reduce postoperative pain and recovery time for patients with perianal fistula after fistulotomy

Public title

Phenytoin ointment in healing anal fistula after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria included: Long-term use of corticosteroids ;diabetes POORLY CONTROL ;TB patients; people with Coron disease; people with underlying malignancy;patients who have had radiation; patients with a history cemothorapy less than 2 weeks; allergy to phenytoin. Inclusion criteria: all patients with anal fistula.

Age

No age limit

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **44**

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

Street address

Mazandaran University of Medical Sciences, beginning
Valiasr Highway, Jouybar three way, Imam Khomeini
square, Sari, Iran

City

Sari

Postal code

4817844718

Approval date

2016-02-21, 1394/12/02

Ethics committee reference number

IR.MAZUMS.REC.94-1598

Health conditions studied

1

Description of health condition studied

anal fistula

ICD-10 code

K60.3

ICD-10 code description

Anal fistula

Primary outcomes

1

Description

wound healing

Timepoint

2,4,6 weeks after surgery

Method of measurement

physical exam

2

Description

fecal and gas incontinency

Timepoint

2,4,6 weeks after surgery

Method of measurement

wexner questioner

3

Description

post operative pain

Timepoint

2,4,6 weeks after surgery

Method of measurement

SELFE RELATED ON A VISUAL ANALOG SCALE

Secondary outcomes

1

Description

anal pruritus

Timepoint

2,4,6 weeks after surgery

Method of measurement

5-D Pruritus Scale

2

Description

wound secretion

Timepoint

2,4,6 weeks after surgery

Method of measurement

physical exam

3

Description

Pain during defecation

Timepoint

2,4,6 weeks after surgery

Method of measurement

SELFE RELATED ON A VISUAL ANALOG SCALE

4

Description

post operative complications

Timepoint

2,4,6 weeks after surgery

Method of measurement

physical exam

Intervention groups

1

Description

All patients treated by probing fistula tract in lithotomy position under spinal anesthesia. Then direction is probe guided and fistulotomy done in its length and preserve sphincter muscles involved in CONTINENCY. then bed of wound currete to remove epithelial lining. Patients are hospitalized for a day. the Topical cream phenytoin 1% used to 2 times a day. for all patients prescribed an oral NSAIDS.

Category

Treatment - Drugs

2

Description

All patients treated by probing fistula tract in lithotomy position under spinal anesthesia. Then direction is probe guided and fistulotomy done in its length and preserve sphincter muscles involved in CONTINENCY. then bed of wound currete to remove epithelial lining. Patients are hospitalized for a day. the Topical placebo used to 2 times a day. for all patients prescribed an oral NSAIDS

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Sari

Full name of responsible person

Dr.M. Alvandipour

Street address

Imam Khomeini Hospital, Amirmazandarany street,Sari,Iran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.R Esmaeili

Street address

Imam (RA) three ways Jooybar, the beginning of the highway Valieasr, Mazandaran University of Medical Sciences

City

Sari

Grant name

10506

Grant code / Reference number

1290007

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of medical science

Full name of responsible person

Dr.M.Alvandipour

Position

Assistant Professor

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact

Name of organization / entity

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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