Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 cemotherapy 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
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Iran (Islamic Republic of)
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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 cemotherapy 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

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Person responsible for updating data

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Name of organization / entity
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Dr.S Namazi Baigi

Position
general surgery resident

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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