Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison between the effects of Topical ointment Sucralfate10% and topical placebo on Wound Healing & Postoperative pain in patients with prianal Fistula after surgery

Protocol summary

Summary

This double blind clinical trial study is based on the patients suffering from perianal fistula whose fistules will be operated in sari Imam khomeini hospital during 1393.We will investigate the effect of sucralfate ointment 10% on post operation pain release and it's role in wound healing compare with the placebo .All the patients will be cured through fistoiotomy by probing the fistula tract under spinal anesthesia in lithotomy position.The pateints will be hospitalized for one day.During the post op period, they will be divided into two groups; the first one will be treated group using placebo and the second one will be the intervening group taking sucralfate10% twice a day.The patients will be visited in 2,4&6 weeks later, and the pain intensity will be recorded based on VAS ,while the amount of the wound healing will also be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041414483N5**
Registration date: **2015-05-08, 1394/02/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-08, 1394/02/18

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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malvandipour@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University Of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the effects of Topical ointment Sucralfate10% and topical placebo on Wound Healing & Postoperative pain in patients with prianal Fistula after surgery

Public title

Effect of sucralfate in treatment of post operation anal fistula wound

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:all the patients whose perianal fistula was operated(fistulotomy) Exclusion criteria:long term consumption of corticosteroid;poorly controlled diabetic patients ;the patient who suffering TB; crohn disease ;malignancy ;radiation therapy ;the patients whose are on chemotherapy and pased less than two weeks after

chemotherapy.

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
Moalem Sq, Sari

City
Sari

Postal code

Approval date
2015-03-04, 1393/12/13

Ethics committee reference number
13/12/1393

Health conditions studied

1

Description of health condition studied
Perianal fistula

ICD-10 code
k60.3

ICD-10 code description
Anal fistula

Primary outcomes

1

Description
Post op pain

Timepoint
2,4,6weeks after intervention

Method of measurement
VAS

2

Description
Wound healing

Timepoint
2,4,6weeks after intervention

Method of measurement
Mucosal coverage of wound

Secondary outcomes

1

Description
Painful deffication

Timepoint
2,4,6weeks after intervention

Method of measurement
VAS

2

Description
Discharge

Timepoint
2,4,6 weeks after intervention

Method of measurement
Visual observation

3

Description
Itching

Timepoint
2,4,6 weeks after intervention

Method of measurement
5-D pruritis scale

4

Description
Post op coplication

Timepoint
2,4,6 weeks after intervention

Method of measurement
Physical examination

5

Description
Side effect of medication

Timepoint
2,4,6 weeks after intervention

Method of measurement
History

6

Description
Post op bleeding
Timepoint
2,4,6weeks after intervention
Method of measurement
Physical examination

7

Description
Fecal incontinency
Timepoint
2,4,6weeks after itervention
Method of measurement
History

8

Description
Gas incontinency
Timepoint
2,4,6 weeks after intervention
Method of measurement
History

9

Description
Couret count
Timepoint
2,4,6 weeks after intervention
Method of measurement
Count number

Intervention groups

1

Description
The control group:taking pelacebo topical ointment vaselin twice daily for 6weeks
Category
Treatment - Drugs

2

Description
The intervention group:taking Topical ointment sucralfat 10% twice daily for 6weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Mina Alvandipour
Street address
Amirmazandarani St, Sari
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr.Ahmadali Enayati
Street address
Moallem Sq, Sari
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
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 Sciences
Full name of responsible person
Dr. Mina Alvandipour
Position
Staff colorectal
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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Hasan Tavakoli

Position

Resident of surgery/Student

Other areas of specialty/work

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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