

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Country

Iran (Islamic Republic of)

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+98 15 1225 6329

Email address

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 passed 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 defecation

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

Other areas of specialty/work

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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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Web page address

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