Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the efficacy of Sodium tetradecyl sulfat 1% and Ceftazidime and Metronidazole in treatment of patients with perianal fistula

Protocol summary

Summary

1- Objectives: comparison of Sodium tetradecyl sulfate1% and Ceftazidime and Metronidazole in management of perianal fistula. 2- Design: randomized clinical trial, not blinded. 3- Setting and conduct: 22 patients with perianal fistula divided into 3 groups randomly. In first group: Sodium tetradecyl sulfate1% and Ceftazidime, in second group: Sodium tetradecyl sulfate1% and Metronidazole and in third group: Ceftazidime and Metronidazole injected in fistula tract. Then compared closing of fistula tract, relief of pain and secretion in 3 groups. 4- Participants: inclusion criteria: perianal fistula in any age and sex. Exclusion criteria: severe systemic disease, pregnancy, breast-fed mothers. 5- Intervention: In first group: Sodium tetradecyl sulfate1% at first day and Ceftazidime at next day injected to fistula tract every other day for 1 week and then 3 times in week until external orifice of fistula closed. In second group: Sodium tetradecyl sulfate1% and Metronidazole and in third group: Ceftazidime and Metronidazole injected in similar style with first group. 6- Main outcome measures variables: recovery of perianal fistula.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051913385N1**
Registration date: **2013-08-07, 1392/05/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-07, 1392/05/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapur University of Medical Sciences, Vice Chancellor for Research and Technology

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Sodium tetradecyl sulfat 1% and Ceftazidime and Metronidazole in treatment of patients with perianal fistula

Public title

The efficacy of Sodium tetradecyl sulfate 1% and Ceftazidime and Metronidazole in perianal fistula

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with perianal fistula. Exclusion criteria: Pregnant or nursing women and patients with severe systemic disease.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Ethics Committee of Jondishapur University of Medical Sciences

Street address

Ahvaz Jondishapur University of Medical Sciences, Golestan avenue

City

Ahvaz

Postal code

1579461257

Approval date

2011-10-15, 1390/07/23

Ethics committee reference number

ETH-259

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

Disappear of fistula tract

Timepoint

Six months after beginning of intervention

Method of measurement

Physical exam with prob

Secondary outcomes

1

Description

Disappear of pain

Timepoint

Six months after beginning of intervention

Method of measurement

History

2

Description

Disappear of discharge

Timepoint

Six months after beginning of intervention

Method of measurement

History and Physical exam

Intervention groups

1

Description

Group 1: one day Sodium tetradecyl sulfate1% (1cc) diluted with 3cc water for injection and next day Ceftazidime (4cc) injected in fistula tract for 1 week, then 3 times in week until recovery occurred. (Sodium tetradecyl sulfate is an Sclerosing agent which is produced in 1 cc vials in saturations %1 and %3. Ceftazidime is a antibiotic with 1g /vial that diluted with water for injection) .

Category

Treatment - Drugs

2

Description

Group 2: one day Sodium tetradecyl sulfate1% (1cc) diluted with 3cc water for injection and next day Metronidazole (4cc) injected in fistula tract for 1 week and then 3 times in week until recovery occurred. (Metronidazole is an antibiotic vial 500 mg / 100 ml) .

Category

Treatment - Drugs

3

Description

Group 3: one day Ceftazidime (4cc) and next day

Metronidazole (4cc) injected in fistula tract for 1 week and then 3 times in week until recovery occurred.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Surgery ward of Imam Khomainy Hospital

Full name of responsible person

Mahtab Farhadi

Street address

Imam Khomainy Hospital, Azadegan avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jondishapur University of Medical Sciences, Vice Chancellor for Research and Technology

Full name of responsible person

Mostafa Feghhi

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Ahvaz Jondishapur University of Medical Sciences, Golestan avenue

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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

Ahvaz Jondishapur University of Medical Sciences, Vice Chancellor for Research and Technology

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

Ahvaz Jondishapur University of Medical Sciences Surgery ward

Full name of responsible person

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Surgery Assistant

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