Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation the effect of treatment by oral antibiotics in patients with pre-anal abscess in occurrence of anal fistula within 3 months post operation.

Protocol summary

Summary

Aims and pattern The most common complications of anorectal abscess are recurrence and fistula formation that happen after standard treatments including incision and drainage. Different participating factors in fistula formation after incision and drainage have been studied among age , sex, race, season of illness, personal hygiene, slow job, bowel habits, diabetes, microbiologic culture, abscess, kind of abscess, smoking, alcohol and pre operation consumption of antibiotics can be mentioned . Regarding to different opinions and high prevalence of disease we decided to compare fistula formation rate in patients receiving antibiotics after surgical treatment of uncomplicated abscess with the group with no given antibiotics . Different antibiotics has been tried in these conditions , but, not only the kind of antibiotics , but also the necessity of giving antibiotics after incision and drainage on anorectal abscess has been debated so far . Program and participants Based on the formula comparing two proportions the sample size has been determined 150 in each group . There are 150 patient in the first group - antibiotic receiving - and 150 in the second group whom were not given any antibiotics after operation (Dividing method was based on the permutation blocks) . Entry in study criteria Age between 16 and 65 – Perianal diagnosis made by general surgery resident – First time arrival with perianal diagnosis . Exclusion criteria Previous anal surgeries – co existing fistula – Inflammatory diseases of bowel – Previous radiation to pelvis – cellulites Interactions In control group : Patients with diagnosed perianal abscess undergo incision and drainage . They receive no additional treatment . In experiment group : Patients undergo incision and drainage and they will be given oral antibiotics (Ciprofloxacin and Clindamycin) 7 days after being discharged from hospital . Main consequent variables Fistula formation rate in the two groups - patient who take oral antibiotics and those who does not - in the time of being sent home after incision and drainage operations will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311049936N7**
Registration date: **2014-01-07, 1392/10/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-01-07, 1392/10/17

Registrant information

Name

Leila Ghahramani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice –Chancellor for research, Shiraz University of Medical Sciences, Shiraz, Iran

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of treatment by oral antibiotics in patients with pre-anal abscess in occurrence of anal fistula within 3 months post operation.

Public title

Effect of treatment with oral antibiotics at discharge rates of anal fistula

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age older than 16 years and less than 65 years; peri-anal abscess diagnosed by a resident of anorectal surgery; the first patient was admitted because of anal abscess. Exclusion criteria: previous anal surgery; there fistula with abscess; inflammatory disease of the colon; history of pelvic radiation, cellulite; horseshoe abscesses; immunosuppression; diabetes mellitus; heart valve disease; prostheses; obesity; history of hypersensitivity to metronidazole and ciprofloxacin; ischiorectal abscess.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

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

Shiraz University of Medical Siences

Street address

Shiraz University of Medical Siences, Shiraz, Iran

City

Shiraz

Postal code

Approval date

2013-06-29, 1392/04/08

Ethics committee reference number

4694-01-01-91

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

Anal fistula treatment with the use of oral antibiotics after discharge

Timepoint

Two weeks after surgery and initial evaluation of patients during the first three months of using oral antibiotics

Method of measurement

Feeding, The recovery rate, The fistula

Secondary outcomes

1

Description

Anal fistula treatment without the use of oral antibiotics after discharge

Timepoint

Two weeks after surgery and initial evaluation of patients during the first three months of using oral antibiotics

Method of measurement

Feeding, The recovery rate, The fistula

Intervention groups

1

Description

Control group: patients with perianal abscess under the standard surgical treatment (incision and drainage) are placed under additional treatment not covered.

Category

Treatment - Drugs

2

Description

Intervention group: patients with perianal abscess under the standard surgical treatment (incision and drainage) is placed at discharge for 7 days, oral antibiotics (ciprofloxacin and metronidazole) is prescribed.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emergency Faqihi hospital, Shiraz, Iran
Full name of responsible person
Dr Leila Ghahramani- Assistant professor of General Surgery
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice –Chancellor of Shiraz University of Medical Sciences, Shiraz, Iran
Full name of responsible person
Dr. Gholamreza Hatam
Street address
Vice –Chancellor of Shiraz University of Medical Sciences, Shiraz, Iran
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Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice –Chancellor of Shiraz University of Medical Sciences, Shiraz, Iran
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

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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