

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

lghahraman@sums.ac.ir

##### 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 Sciences

**Street address**  
Shiraz University of Medical Sciences, 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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Colorectal Research Center, Faghihi hospital, Shiraz, Iran

**City**

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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

**City**

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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**

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****Contact****Name of organization / entity**

Colorectal Research Center, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Safarpour

**Position**

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|-----------------------------------------------------------|------------------------------|
| <b>Web page address</b>                                   | <i>empty</i>                 |
| <b>Sharing plan</b>                                       | <b>Informed Consent Form</b> |
|                                                           | <i>empty</i>                 |
| <b>Deidentified Individual Participant Data Set (IPD)</b> | <b>Clinical Study Report</b> |
| <i>empty</i>                                              | <i>empty</i>                 |
| <b>Study Protocol</b>                                     | <b>Analytic Code</b>         |
| <i>empty</i>                                              | <i>empty</i>                 |
| <b>Statistical Analysis Plan</b>                          | <b>Data Dictionary</b>       |
|                                                           | <i>empty</i>                 |