Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of fistulectomy method and ligation of internal orifice in treatment of complex perianal fistula as a new method.

Protocol summary

Summary

Anal fistula including common and debilitating disease that is characterized by severe pain and discharge. For many years, the treatment of choice for this disease remains to be Fystulectomy, while this approach in cases of complex fistulas and high fistulas leads to incontinence and potentially damaging consequences. Alternative therapies in the treatment of fistulas have also had little success. The aim of this study was to evaluate the results of fystulectomy with closing the internal opening and sphincter repair as a novel treatment is the cases of complex fistulas. This study is a prospective study which was conducted in Besat educational & medical center of Hamadan medical university. All patients with complex anal fistulas from October 2006 to October 2011 were entered the study and underwent fystulectumy surgery with closure of internel opening.Low rate of incontinence was measured with a standard wexner scale. Early complications after surgery were investigated before discharge and one week after surgery. The incidence of incontinence and recurrence after 3 and 6 months of follow-up period, were evaluated.Wexner quantitative measure of incontinence was evaluated using a standard Wexner scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122011591N1**
Registration date: **2013-04-14, 1392/01/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-04-14, 1392/01/25

Registrant information

Name
Hamid Esmailpoor
Name of organization / entity
Hamedan University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Sponsored by research deputy of Hamedan University of Medical Science.

Expected recruitment start date

2012-06-04, 1391/03/15

Expected recruitment end date

2012-12-05, 1391/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of fistulectomy method and ligation of internal orifice in treatment of complex perianal fistula as a new method.

Public title

New Fistulectomy method in treatment of patients with complex perianal fistula.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Anal fistula : high anal fistula; complex anal fistula. Exclusion:Anal fistula : low anal fistula;

history of incontinance; Perevious sphingter injery.

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Science

Street address

Shahid Fahmide St.

City

Hamedan

Postal code

65178

Approval date

2012-04-22, 1391/02/03

Ethics committee reference number

245/9/35/16/د/پ

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

Recurrance of desease

Timepoint

in 3 and 6 mons follow up period

Method of measurement

Physical examination

2

Description

Incontinance

Timepoint

after sugery and 3 & 6 mons later

Method of measurement

Jorge-Wexner scale

Secondary outcomes

1

Description

Complications

Timepoint

After surgery and 3 & 6 mons later

Method of measurement

Physical examination

Intervention groups

1

Description

Fistulectomy method and ligation of internal orifice

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat Hospital, Booali hospital of Hamedan

Full name of responsible person

Street address

Beasat hospital, Resaalat sq.

City

Hamedan

2

Recruitment center

Name of recruitment center

Besat Hos.

Full name of responsible person

Hamid Esmailpoor

Street address

Surgery Departman Besat Hos.

City

Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Hamedan University of Medical Science
Full name of responsible person
Mrs Azimi
Street address
Central site of Hamedan university of medical science
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Hamedan University of Medical Science
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
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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