

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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 in 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 fystulectomy surgery with closure of internal 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

Country

Iran (Islamic Republic of)

Phone

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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; Pervious sphingter injury.

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**Name of organization / entity**

Hamedan University of Medical Science

Full name of responsible person

Hamid Esmailpoor

Position

Surgery resident

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Hamedan University of Medical Science

Full name of responsible person

Nazila Hasanzadeh Ghavifekr

Position

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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