

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

the evaluation of early and late hemorrhoidectomy complications in conventional and ligasure technique

Protocol summary

Summary

The aim of this study is to investigate the complications of conventional and LigaSure hemorrhoidectomy techniques. The method is analytical study (clinical trial) and will be done on about 100 patients 19-80 years old both gender with III, IV-degree hemorrhoids in Shahid Sadoughi hospital. About one half of patients will be treated by conventional diathermy and the others by LigaSure. Patients will receive analgesic administration (IV) for about 24 hours after operations and, after hospital discharge with oral Nsaid, analgesia will be administered until 5 days.(three times a day). All patients require to record pain from the first postoperative day until the 28th postoperative day on a self-administered NAS scale. Patients will be assessed with questioner, face to face one week, one month, six, and twelve months after the operation. The patients will be evaluated on the basis of the following main outcomes: mean operative time, postoperative pain (score and duration), bleeding loss in operation, early (within the first month after surgery) and late (after the first month) complications in conventional and LigaSure hemorrhoidectomy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014022816773N1**

Registration date: **2014-04-19, 1393/01/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-19, 1393/01/30

Registrant information

Name

Naeimeh Heiranizadeh

Name of organization / entity

Shahid Sadoughi university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1823 2170

Email address

naeimeh_heiranizadeh@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Residents Grant of Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2011-04-04, 1390/01/15

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the evaluation of early and late hemorrhoidectomy complications in conventional and ligasure technique

Public title

compare of hemorrhoidectomy complications in conventional and ligasure technique

Purpose

Treatment

Inclusion/Exclusion criteria

patients in our literature have grade III,IV symptomatic internal hemorrhoid that need to surgery in shahid sadoughi hospital in 1390_91. patients whome had anorectal disease ago , have others anorectal

diseases, recurrence hemorrhoid and don't want to attend delete from this study.

Age

From **19 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **101**

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

shahid sadoughi university of medical sciences

Street address

Shahid Bahonar Square, Shahid sadoughi street, central building

City

Yazd

Postal code

Approval date

2011-11-28, 1390/09/07

Ethics committee reference number

107720

Health conditions studied

1

Description of health condition studied

Haemorrhoid

ICD-10 code

I84

ICD-10 code description

Haemorrhoids

Primary outcomes

1

Description

The post operation pain

Timepoint

Every day until 28th day, after a week, after a month, after six months and after one year

Method of measurement

In terms of Numerical Pain Score

2

Description

Bleeding during operation

Timepoint

Only during the operation

Method of measurement

The number of blood Gauze

3

Description

The time of operation

Timepoint

During operation

Method of measurement

In minutes

Secondary outcomes

1

Description

The time of return to work

Timepoint

a week, a month, six months and 12 months

Method of measurement

Questionnaire and face to face in days

2

Description

Pain score

Timepoint

a week, a month, six months and one year

Method of measurement

numerical pain score with questionnaire and face to face

3

Description

Anal stenosis

Timepoint

numerical pain score

Method of measurement

PH/E, HX (DRE)

Intervention groups

1

Description

LigaSure hemorrhoidectomy: The patients are

anesthetized general or spinal. Position is lithotomy. We use disposable thyroid LigaSure from Covidien Company with the size of 17 cm and its grade of temperature is 2. By using great retractor during surgery LigaSure forceps lay on vascular pedicle level and scissor tissue cut coagulated line. We do not transfixation and it left open. Finally we insert hemostasis sponge in to anal canal.

Category

Treatment - Surgery

2

Description

The patients are anesthetized general or spinal. Position is lithotomy. By using great retractor during surgery we incise hemorrhoidal pile above the dentate line with scissor tissue. With blunt dissection internal sphincter muscle separated from hemorrhoidal pile. With absorbable cotton, pile transfixes and cut and also Hemostasis is achieved. It left open in open technique and repairs with absorbable cotton in close technique. Finally we insert hemostasis sponge in to anal canal.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Naeimeh Heiranizadeh

Street address

Shahid Sadoughi University of Medical Sciences

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Mrs Ayazi

Street address

Central building, Shahid Sadoughi Blvd, Bahonar Sqr.

City

Yazd

Grant name

بودجه پژوهانه

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd Shahid Sadoughi University of Medical Sciences

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

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Mohammad Zare

Position

University teacher

Other areas of specialty/work

Street address

Yazd Shahid Sadoughi Hospital

City

Yazd

Postal code

Phone

+98 35 1822 4000

Fax

Email

mohammadzare85@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd Shahid Sadoughi university of medical science

Full name of responsible person

Naeimeh Heiranizadeh

Position

Surgery Resident

Other areas of specialty/work

Street address

Yazd Shahid Sadoughi university of medical science
Pardis, Shohadaye Gornam Blvd, Prof. Hesabi Blvd.

City

Yazd

Postal code

Phone

+98 35 1822 4000

Fax

Email

Naeimeh_heiranizedeh@ssu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Naeimeh Heiranizadeh

Position

Surgery Resident

Other areas of specialty/work

Street address

Yazd Shahid Sadoughi university of medical science,
Shohadaye Gomnam Blvd, Prof. Hesabi Blvd.

City

Yazd

Postal code

Phone

+98 35 1823 2170

Fax

Email

naeimeh_heiranizadeh@ssu.ac.ir

Web page address

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