

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Assessing the impact of stapled hemorrhoidopexy on stool continence in patients with hemorrhoids

Protocol summary

Summary

Objective: efficacy and safety of stapled hemorrhoidopexy on incontinence. Design: observational model, cohort Time Perspective: Prospective Setting and conduct: Patients will be assessed for incontinence 3 month after stapled hemorrhoidopexy by anal manometry and Wexner score. Inclusion criteria: patients undergoing stapled hemorrhoidopexy for rectal prolapse and/or hemorrhoid grade III or IV Exclusion criteria: younger than 18 or experiencing more than 80 times history of incontinence, diabetic mellitus and neurological disease. Intervention: patients will undergo stapled hemorrhoidopexy. Main outcome measures: incontinence, anal manometry and Wexner score, bleeding, time of operation, site of stapler line. Hemorrhoids are a worldwide benign anorectal disease. Stapled hemorrhoidopexy for third and fourth degree hemorrhoids and prolapse has been widely used since 1998. This method has less pain and discharge in comparison to previous traditional methods. Yet, stapled hemorrhoidopexy have complications such as bleeding, incontinence, stricture, fistula, and rupture. We will perform an analysis of a prospective data set of all patients undergoing stapled hemorrhoidopexy in our patients. Patients will be specifically assessed for complications of incontinence 3 months after the operation. Anal manometry and Wexner score was determined before and 3 months after the operation.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015101324504N1**

Registration date: **2016-06-18, 1395/03/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-18, 1395/03/29

Registrant information

Name

Seyed Vahid Hosseini

Name of organization / entity

Colorectal Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 1453

Email address

hoseiniv@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the impact of stapled hemorrhoidopexy on stool continence in patients with hemorrhoids

Public title

Assessing the impact of stapled hemorrhoidopexy on stool continence in patients with hemorrhoids

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: age more than 18 and lesser than 80; patients with hemorrhoids grade 3 or 4; patients with prolapsed and/or hemorrhoids grade 3 or 4 Exclusion criteria: Patients with fecal incontinence; patients with diabetes; patients with neurological disease.

Age

From **17 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz university of Medical Sciences, Shiraz, Iran

Street address

Vice-chancellor for research of Shiraz university of Medical Sciences, Shiraz, Iran

City

Shiraz

Postal code

Approval date

2015-09-13, 1394/06/22

Ethics committee reference number

IR.sums.REC.1394.106

Health conditions studied

1

Description of health condition studied

Fecal incontinence

ICD-10 code

R15

ICD-10 code description

Faecal incontinence

Primary outcomes

1

Description

Fecal incontinence

Timepoint

Before surgery and 3 months after surgery

Method of measurement

with Manometry and Wexner score.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients with inclusion criteria will be evaluated for manometry and Wexner score before surgery. To evaluate the anal function, a validated Wexner incontinence scale score system (total incontinence score 0: best and 20: worst) and anal manometric indices will be measured 1 day before the surgery and 3 months after the operation. The Wexner scale was described by Wexner and Jorge and consisted of items about frequency of gas and fecal incontinence. Anal manometric measures and Wexner scores will be compared pre- and postoperatively. For doing anorectal manometry, the patient will be positioned in left lateral decubitus with knees flexed. For anal manometry, a Sphinctrometer system (MSM Promedico GmbH) will be used. After calibration, a probe will be introduced into the rectal ampulla up to 6 cm from the anal verge. Anal resting Pressure (ARD), anal maximum squeezing pressure (AMD), and Mean pressure will be calculated.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari hospital, Shiraz University of Medical Sciences

Full name of responsible person

Mehdi Tahamtan, Dr

Street address

Shahid Motahari Hospital, Zand street, Shiraz, Iran

City

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2

Recruitment center

Name of recruitment center

Shahid Faghihi hospital, Shiraz university of Medical Sciences

Full name of responsible person

Mehdi Tahamtan, Dr

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz university of Medical Sciences, Shiraz, Iran

Full name of responsible person

Seyed Basir Hashemi, Dr

Street address

Vice-chancellor for Shiraz university of Medical Sciences, Shiraz, Iran

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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

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, Shiraz, Iran

Full name of responsible person

Mehdi Tahamtan, Dr

Position

General Surgeon, Colorectal surgery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Professor Seyed Vahis Hosseini

Position

Professor of General Surgery, Flowship of Colorectal Surgery

Other areas of specialty/work

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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