

# 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**

Shiraz

### **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**

Shahid Faghihi hospital, Zand Street, Shiraz, Iran

**City**

Shiraz

## 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

**City**

Shiraz

**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**

**Street address**

Colorectal Research Center, Mohammad Rasolalah Research Tower

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Colorectal Research Center, Shiraz University of Medical Sciences

**Full name of responsible person**

Professor Seyed Vahis Hosseini

**Position**

Professor of General Surgery, Flowship of Colorectal Surgery

**Other areas of specialty/work**

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## Person responsible for updating data

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

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**Other areas of specialty/work**

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**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*