

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The efficiency of endoscopic resection of polypoid solitary rectal ulcer syndrome (SRUS) compared to Delorme's procedure: A clinical trial.

Protocol summary

Study aim

The purpose of this clinical trial is to assess the effectiveness of endoscopic resection in alleviating the symptoms of patients suffering from polypoid solitary rectal ulcer syndrome and compare it with Delorme's procedure.

Design

Clinical trial with control group, with parallel groups, without blinding, and randomized. A sealed envelope was used for randomization.

Settings and conduct

Patients with polypoid type of solitary rectal ulcer syndrome, referring to Taleghani Hospital in Tehran, will receive one of the interventions randomly in two groups of 25 people.

Participants/Inclusion and exclusion criteria

Inclusion criteria were: symptoms such as rectorrhagia, mucosal discharge, dyschezia, rectal tenesmus, or the need for anal digitation; Confirmation of polypoid solitary rectal ulcer syndrome in colonoscopy and pathology prepared from biopsy. Exclusion criteria were: High-risk patients for anesthesia; Patients taking warfarin; Patients who should not have their polyps removed; Patients with cardiovascular disorders; Patients with coagulation problems; People with systemic diseases; Patients who cannot diet; Patient's non-cooperation; Failure to attend for biofeedback; Patients for whom biofeedback treatment is not effective.

Intervention groups

One group of patients underwent endoscopic resection and the other group, as a control group, underwent surgical intervention with the Delorme procedure.

Main outcome variables

Clinical manifestations

IRCT registration information

IRCT registration number: **IRCT20211101052935N2**

Registration date: **2023-01-22, 1401/11/02**

Registration timing: **retrospective**

Last update: **2023-01-22, 1401/11/02**

Update count: **0**

Registration date

2023-01-22, 1401/11/02

Registrant information

Name

Mohsen Rajabnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1799

Email address

dr.rajabnia@outlook.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-16, 1395/12/26

Expected recruitment end date

2021-12-30, 1400/10/09

Actual recruitment start date

2017-06-18, 1396/03/28

Actual recruitment end date

2021-10-16, 1400/07/24

Trial completion date

2022-09-17, 1401/06/26

Scientific title

The efficiency of endoscopic resection of polypoid solitary rectal ulcer syndrome (SRUS) compared to Delorme's procedure: A clinical trial.

General information

Reason for update

Acronym

Public title

Solitary rectal ulcer endoscopic trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

symptoms such as rectorrhagia, mucosal discharge, dyschezia, rectal tenesmus, and the need for anal digitation Confirmation of polypoid solitary rectal ulcer syndrome in colonoscopy and pathology prepared from biopsy

Exclusion criteria:

High-risk patients for anesthesia Patients taking warfarin Patients who should not have their polyps removed Patients with cardiovascular disorders Patients with coagulation problems People with systemic diseases Patients who cannot diet Patient's non-cooperation Failure to attend for biofeedback Patients for whom biofeedback treatment is not effective

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with a sealed previously prepared envelope

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**

Ethics committee of Shahid Behrshti University of Medical Sciences

Street address

Ayatollah Taleghani Hospital, Shahid Arabi Ave., Yaman St., Shahid Chamran Highway, Tehran.

City

Tehran

Province

Tehran

Postal code

1985711151

Approval date

2021-12-15, 1400/09/24

Ethics committee reference number

IR.SBMU.RIGLD.REC.1400.024

Health conditions studied**1****Description of health condition studied**

Polypoid variant of rectal solitary ulcer syndrome

ICD-10 code

K62.6

ICD-10 code description

Ulcer of anus and rectum

Primary outcomes**1****Description**

The patient's clinical symptoms including rectorrhagia, obstruction, rectal tenesmus, anal digitation, painful defecation, and mucus defecation.

Timepoint

At the beginning of the study (before the start of the intervention), 1 month, 3 months, 6 months, 1 year, 2 years, and 3 years after the procedure

Method of measurement

Questions about the patient's symptoms and checklist

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Endoscopic polypoid resection as a novel low-risk and low-complication surgical method

Category

Treatment - Surgery

2**Description**

Control group: Delorme procedure as one of the standard methods of treatment of solitary rectal ulcer syndrome

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center**

Name of recruitment center

Taleghani hospital-Tehran

Full name of responsible person

Mohsen Rajabnia

Street address

Gastroenterology and Liver Diseases Research
Institute, No 1, Ayatollah Taleghani Hospital, Shahid
Arabi Ave., Yaman St., Shahid Chamran Highway,
Tehran.

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Email

dr.rajabnia@outlook.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mojgan Forootan

Street address

Gastroenterology and Liver Diseases Research
Institute, No 1, Ayatollah Taleghani Hospital, Shahid
Arabi Ave., Yaman St., Shahid Chamran Highway,
Tehran.

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 912 326 5382

Email

mojganforootan@sbmu.ac.ir

Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Doctor Mojgan Forootan

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohsen Rajabnia

Position

Adult gastroenterology and hepatology subspecialist
assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Gastroenterology and Liver Diseases Research
Institute, No 1, Ayatollah Taleghani Hospital, Shahid
Arabi Ave., Yaman St., Shahid Chamran Highway,
Tehran.

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Email

dr.rajabnia@outlook.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohsen Rajabnia

Position

Gastroenterology and hepatology subspecialist
assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Gastroenterology and Liver Diseases Research
Institute, No 1, Ayatollah Taleghani Hospital, Shahid
Arabi Ave., Yaman St., Shahid Chamran Highway,
Tehran.

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Email

dr.rajabnia@outlook.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Erfan Ghadirzadeh

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Sari, Amir Mazandarani Street, Imam Khomeini
Hospital, Gastroenterology and Liver Diseases
Research Institute

City

Sari

Province

Mazandaran

Postal code

4816117949

Phone

+1133033406

Email

e.ghadirzadeh@mazums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only a portion of the potential data related to the primary outcome can be shared after de-identifying individuals.

When the data will become available and for how long

After publishing the article

To whom data/document is available

The data will be available to researchers

Under which criteria data/document could be used

It can be used in secondary studies or studies with Bayesian analysis

From where data/document is obtainable

After publication of the article resulted from this data, they can make contact with the corresponding author to receive the documents: Dr. Mojgan Forootan
mfrootan2003@yahoo.com +989123265382

What processes are involved for a request to access data/document

After receiving the email, the requested information will be sent in less than a week.

Comments