

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of outcomes between Postanal Repair and levatoroplasty in Treatment of Rectal Prolapse

#### Protocol summary

##### Study aim

The effect of post-anal repair and levatoroplasty in the treatment of rectal prolapse by Eltmayer surgery

##### Design

Clinical trial with control group, with parallel groups, double-blind, simple randomized

##### Settings and conduct

The study was conducted in Imam Khomeini Hospital in Sari and the data collection locations were in Imam Khomeini Hospital in Sari and the Colorectal Surgery Clinic. The surgeon knows. This study is double blind

##### Participants/Inclusion and exclusion criteria

Entry requirements: patients between 18 and 80 years old, patients who have consented to the study, patients who are candidates for Altemeier restoration  
Exclusion conditions: patients who have not consented to participate in the study, patients who are candidates for rectal prolapse repair with other methods, previous prolapse surgery history

##### Intervention groups

Post-anal repair and levatoroplasty in the treatment of rectal prolapse using the Eltmayer surgery method is performed based on the surgeon's judgment during the operation for patients with thin and weak levatorian muscles.

##### Main outcome variables

Improvement of the patient's symptoms and incontinence after surgery in two groups with or without post-anal repair and levatoroplasty. Rectal prolapse recurrence rate after surgery in two groups with or without post-anal repair and levatoroplasty.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130826014483N11**

Registration date: **2022-12-14, 1401/09/23**

Registration timing: **retrospective**

Last update: **2022-12-14, 1401/09/23**

Update count: **0**

##### Registration date

2022-12-14, 1401/09/23

##### Registrant information

###### Name

Mina Alvandipour

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1225 6329

###### Email address

malvandipour@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-04, 1400/11/15

##### Expected recruitment end date

2022-11-21, 1401/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of outcomes between Postanal Repair and levatoroplasty in Treatment of Rectal Prolapse

##### Public title

Comparison between Postanal Repair and levatoroplasty in Treatment of Rectal Prolapse

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients 18 to 80 years old Patients who have consented to the implementation of the study Patients who are candidates for Altemeier restoration

### Exclusion criteria:

Patients who did not consent to participate in the study Patients who are candidates for rectal prolapse repair with other methods

## Age

From **18 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

After applying the entry and exit criteria, subjects will be randomly assigned using permutation blocks. By using Sealedenvelop.com software, a sequence of size 80 will be produced. The randomization unit is an individual. The size of the blocks is 4 and in each block each intervention group will be repeated twice (the randomization ratio in each block is 1:1). Using this randomly generated list, the participants are assigned to one of the two study groups. In order to hide the list of random allocation, a special code will be assigned to each of the intervention groups, which even the main implementer of the project (supervisor) is not aware of. These codes are written on a paper and placed inside a sealed envelope. A unique code specific to each patient will be written on this paper and its envelope. All envelopes will be placed in a larger box in random order and sealed in the box. The main researcher, after reviewing the criteria for entering the study and obtaining informed consent, as well as registering the patient's profile in a special form, in collaboration with the random allocation list (this person is an expert, other than the main researcher, who is involved in the patient recruitment process and sample entry) is called and randomization of that patient is done.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The study is blinded from the point of view of the patients and the evaluator, and the patient and the evaluator are not aware of the results and complications after the operation of the groups, but the surgeon knows.

This study is double blind

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee in research of Imam (RA) Sari Educational and Therapeutic Hospital - Mazandaran Uni

##### Street address

Amir Mazandarani Blvd

##### City

Sari

##### Province

Mazandaran

##### Postal code

33131 - 48166

#### Approval date

2022-02-02, 1400/11/13

#### Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1400.073

## Health conditions studied

### 1

#### Description of health condition studied

Rectal prolapse

#### ICD-10 code

K62.3

#### ICD-10 code description

Rectal prolapse

## Primary outcomes

### 1

#### Description

Improvement of patient's symptoms and incontinence after discomfort in two groups of Baya without post-anal repair and levatoroplasty

#### Timepoint

Patients are followed up in six times, one time before surgery and five times after surgery.

#### Method of measurement

questionnaire

### 2

#### Description

The recurrence rate of rectal prolapse after surgery in

two groups with or without post-anal repair and levatoroplasty

#### **Timepoint**

Patients are followed up in six times, one time before surgery and five times after surgery.

#### **Method of measurement**

questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Anastomotic dehiscence, stenosis, 3-month mortality after Eltamayer Bayabadon post-anal repair and levatoroplasty surgery

#### **Timepoint**

Patients are followed up in six times, one time before surgery and five times after surgery.

#### **Method of measurement**

questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Before the operation, prophylactic antibiotics and laxatives are prescribed for the patients to keep the intestines clean. Eltmeyer surgery is a procedure in which the part of the rectum protruding from the anal canal is resected and the remaining two ends of the intestine are anastomosed to each other. 2 mg of fentanyl and midazolam were used for anesthesia and 3 to 5 mg/kg sodium thiopental was used to induce anesthesia, then intubation was performed, then anesthesia was continued with 3% isoflurane. The patients are placed in the lithotomy position, the prolapsed rectum is pulled out towards the perineum with the help of a retractor, then the intestinal mucosa is cut circularly 1-2 cm above the dentate line, when separating the muscle layer, the homeostasis of the submucosa layer is ensured. Then the rectum is pulled down to reveal the rectovaginal peritoneal fold. At this time, the peritoneum is opened from the anterior and lateral parts until the sigmoid colon is pulled down and the location of the intestinal tract is determined. The sigmoid mesentery is also separated and ligated. An incision is made in the anterior part of the sigmoid colon, here the first anastomotic sutures are created, then the same is done for the lateral and posterior parts of the sigmoid colon. Colon-anal anastomosis is reinforced with multiple sutures. Anastomosis can be performed with the help of a circular stapler depending on the conditions and decision of the surgeon. In order to repair the pelvic floor (levatoroplasty) after the mesorectal dissection, the posterior wall of the vagina is dissected along with the fat tissue of the Douglas pouch so that the slings of the levator ani muscles appear. The sutures are pulled up from the peritoneum to the anterior wall of the sigmoid pouch of Douglas, and finally, the two arms of the levator ani muscle are connected in the midline and in front of

the intestine with previous sutures, and the gap created in the pelvic diaphragm is repaired with anterior levatoroplasty. . This repair is usually done based on the surgeon's judgment during the operation for patients with narrow and weak levatorian muscles.

#### **Category**

Treatment - Surgery

### **2**

#### **Description**

Control group: A group in which post-anal repair surgery and levatoroplasty are not performed

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Imam khomeyni hospital

##### **Full name of responsible person**

Dr.Mina Alvandipour

##### **Street address**

Amirmazandarani St, Sari

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

33131 - 48166

##### **Phone**

+98 11 3336 1700

##### **Fax**

+98 11 3336 1700

##### **Email**

malvandipour@mazums.ac.ir

##### **Web page address**

<https://www.mazums.ac.ir/>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Mazandaran University of Medical Sciences

##### **Full name of responsible person**

Majid Saedi

##### **Street address**

Joybar intersection of Mazandaran University of Medical Sciences

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

48157-33971

##### **Phone**

+98 11 3325 7230

**Fax**  
+98 11 3325 7230  
**Email**  
m.saedi@mazums.ac.ir  
**Web page address**  
<https://www.mazums.ac.ir>  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Mazandaran University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr.Mina Alvandipour  
**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
Amirmazandarani St, Sari  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
33131 - 48166  
**Phone**  
+98 11 3336 1700  
**Fax**  
+98 11 3336 1700  
**Email**  
malvandipour@mazums.ac.ir  
**Web page address**  
<https://www.mazums.ac.ir>

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**

Dr.Mina Alvandipour  
**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
Amirmazandarani St, Sari  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
33131 - 48166  
**Phone**  
+98 11 3336 1700  
**Fax**  
+98 11 3336 1700  
**Email**  
malvandipour@mazums.ac.ir  
**Web page address**  
<https://www.mazums.ac.ir>

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr.Mina Alvandipour  
**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
Amirmazandarani St, Sari  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
33131 - 48166  
**Phone**  
+98 11 3336 1700  
**Fax**  
+98 11 3336 1700  
**Email**  
malvandipour@mazums.ac.ir  
**Web page address**  
<https://www.mazums.ac.ir>

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be a plan to make this available  
**Study Protocol**  
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

make this available

**Analytic Code**

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

**Data Dictionary**

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