Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of outcomes between Postanal Repair and levatorplasty 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 levatorplasty.

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

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Mina Alvandipour

Name of organization / entity
Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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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 levatorplasty in Treatment of Rectal Prolapse

Public title
Comparison between Postanal Repair and levatorplasty 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
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Sari
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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 (levatorplasty) 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

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Sponsors / Funding sources

1

Sponsor

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Mazandaran University of Medical Sciences

Full name of responsible person

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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
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
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Person responsible for updating data

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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