Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Evaluation of complications in two rectopexy techniques, mesh rectopexy and open posterior sacral rectopexy in children

Protocol summary

Study aim
Evaluation of complications in two rectopexy techniques, mesh rectopexy and open posterior sacral rectopexy in children
Design
Two arm parallel group randomised trial with blinded researcher and outcome assessment Simple randomization, 25 cases in each groups,
Settings and conduct
Two groups of children with refractory prolapse referred to Tabriz Children's hospital, the first group is case group (mesh rectopexy) and the other group is control group (open posterior sacral rectopexy). Patients and researchers are not aware of groups.
Participants/Inclusion and exclusion criteria
Exclusion criteria: History of underlying disease such as cystic fibrosis, allergy to cow's milk and parasitic diseases such as Trichiura Trichuris. History of previous anorectal surgery such as anoplasty and Hirschsprung's disease. Other rectal diseases such as colitis and polyp and solitary rectal ulcer and colorectal tumors Severe malnutrition.
Intervention groups
Intervention group 1: mesh rectopexy. Intervention group 2: open posterior sacral rectopexy
Main outcome variables
Surgical complications

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150124020767N2**
Registration date: **2020-02-18, 1398/11/29**
Registration timing: **retrospective**

Last update: **2020-02-18, 1398/11/29**
Update count: **0**
Registration date
2020-02-18, 1398/11/29

Registrant information
Name
masoud jamshidi
Name of organization / entity
tabriz medical sciences university
Country
Iran (Islamic Republic of)
Phone
+98 41 3526 2257
Email address
jamshidim@tbzmed.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-03-20, 1395/01/01
Expected recruitment end date
2020-01-13, 1398/10/23
Actual recruitment start date
2016-03-20, 1395/01/01
Actual recruitment end date
2020-01-13, 1398/10/23
Trial completion date
2020-03-19, 1398/12/29

Scientific title
Evaluation of complications in two rectopexy techniques, mesh rectopexy and open posterior sacral rectopexy in children

Public title
evaluation of mesh rectopexy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Children with refractory prolapse (including constipation and other predispositions) after one year medical treatment.

Exclusion criteria:

History of underlying disease such as cystic fibrosis, allergy to cow's milk and parasitic diseases such as Trichiura Trichuris. History of previous anorectal surgery such as anoplasty and Hirschsprung's disease Other rectal diseases such as colitis and polyp and solitary rectal ulcer and colorectal tumors Severe malnutrition.

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **25**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization.Patients receive a number, respectively, in the study, and the odd numbers place in the control group and the even numbers in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients, the researcher, and the analyzer are not aware of the groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Daneshgah St.

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Approval date

2015-02-15, 1393/11/26

Ethics committee reference number

IR.TBZMED.REC.1395.553

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

Complication rate of prolapse repair

Timepoint

Complication rate after surgery

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mesh rectopexy: Patients with refractory rectal prolapse to conservative management will be included in the study. In the case group, the mesh rectopexy procedure (using ribbon like sterile gauze) is performed. In this method, the perineal incision is made transversely as long as two centimeters between anus and coccyx. The longitudinal incision is then made in the pelvic diaphragm without damage to the muscles. A space is created in the retro-rectal area in the areolar tissue from anus to the sacrum promontory. This space opens and encompasses the posterior half of the rectum. Then the space is filled with about two meters of tape mesh and dressing is done. After a week the mesh will be removed and the wound will close spontaneously. The fibrosis created in this space causes the rectum to be fixed and not exit from anus. Post-operatively , patients will visit in the following day, the following week, and three months later, at the end of the first year. Findings and complications that were recorded in a questionnaire, compared with the control group. Statistical findings will be reviewed and published.

Category

Treatment - Surgery

2

Description
Control group: open posterior sacral rectopexy or standard method(Ashcraft technique): Patients with refractory rectal prolapse to conservative management will be included in the study. This procedure involves incising over sacrum bone and opening the pelvic space up to two centimeters from anus. The coccyx bone is removed. Rectum is separated from the sacrum. The meso-rectum is then destroyed. The rectum is fixed with a few sutures to the sacrum bone to prevent the rectum from descending and exiting from anus. The layers are closed in sequence and the operation is terminated. Post-operatively , patients will visit in the following day, the following week, and three months later, at the end of the first year. Findings and complications that were recorded in a questionnaire, compared with the control group. Statistical findings will be reviewed and published.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Children's Hospital

Full name of responsible person
Masoud Jamshidi

Street address
Shesglan St.

City
Tabriz

Province
East Azarbaijan

Postal code
5136735886

Phone
+98 41 3526 2257

Email
Masoudjamshidi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Samiei.mohammad

Street address
Daneshgah St.

City
Tabriz

Province
East Azarbaijan

Postal code
5136735886

Phone
+98 41 3335 7310

Email
research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Masoud Jamshidi

Position
Assissted prof.

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

Street address
Sheshglan st.

City
Tabriz

Province
East Azarbaijan

Postal code
5136735886

Phone
+98 41 3526 2250

Email
Masoudjamshidi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Masoud Jamshidi

Position
Assissted professor

Latest degree
Subspecialist

Other areas of specialty/work
pediatric surgery

Street address
Sheshglan
City
Tabriz
Province
East Azarbaijan
Postal code
5136735886
Phone
0098415262250
Email
Masoudjamshidi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Masoud Jamshidi
Position
Assissted professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Sheshglan
City
Tabriz
Province
East Azarbaijan
Postal code
5136735886
Phone
+98 41 3526 2250
Email
Masoudjamshidi@gmail.com

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
Yes - There is a plan to make this available
Title and more details about the data/document
All collected deidentified IPD
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
N/A
From where data/document is obtainable
Email
What processes are involved for a request to access data/document
As soon as possible
Comments