

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects of glycerol and sodium pentaborate formulation on prevention of postoperative peritoneal adhesion formation

Protocol summary

Study aim

Determining the effect of glycerol and sodium pentaborate formulation in preventing postoperative peritoneal adhesion

Design

A concealed, phase 2, randomized, triple blinded, controlled clinical trial with a parallel group design of 40 patients. RAS (Random Allocation Software) software was used to randomize.

Settings and conduct

40 adults aged 20 to 60 years who need laparotomy for a second look surgery for reverse colostomy or ileostomy will be included in the study and randomly allocated into two groups 1. Intervention (washing the peritoneal area with 100 ml of 3% glycerol and sodium pentaborate 3% formulation at the beginning and end of surgery) and 2. Placebo (washing the peritoneal area with 100 ml of normal saline at the beginning and end of surgery). To concealment the allocation, similar sealed envelopes will be used in a matte package that is numbered one after the other. Main investigators, participants and outcome evaluators will be blind to the random allocation of groups.

Participants/Inclusion and exclusion criteria

Age of 20-60 years and needing laparotomy for reverse colostomy or ileostomy surgery

Intervention groups

Intervention group: Wash the peritoneal area with 100 ml of 3% glycerol and 3% sodium pentaborate formulation at the beginning and end of surgery. Control group: Wash the peritoneal area with 100 ml of normal saline at the beginning and end of surgery

Main outcome variables

Microscopic peritoneal adhesion and gross peritoneal adhesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043923N5**

Registration date: **2020-05-09, 1399/02/20**

Registration timing: **prospective**

Last update: **2020-05-09, 1399/02/20**

Update count: **0**

Registration date

2020-05-09, 1399/02/20

Registrant information

Name

Dawood Aghamohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 1928

Email address

aghamohammadi.d@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-20, 1399/02/31

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of glycerol and sodium pentaborate formulation on prevention of postoperative peritoneal adhesion formation

Public title

Glycerol and sodium pentaborate in prevention of postoperative peritoneal adhesion

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 20-60 years Need laparotomy for reverse colostomy or ileostomy surgery

Exclusion criteria:

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

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

A block randomization method will be used to allocate participants to the groups with a 1:1 allocation using random allocation software (RAS) with block sizes of 2 and 4. Similar sealed envelopes will be used to conceal the allocation in a sequentially numbered opaque package

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, main investigators, physicians in charge of patient care, data collection authorities, those who evaluate the outcome, those who perform the statistical analysis of the data, and those who prepare the draft of the manuscript will be blind to the random allocation of patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical

Sciences

Street address

Emam Reza hospital, Golgasht Str., Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

3265985258

Approval date

2020-04-20, 1399/02/01

Ethics committee reference number

IR.TBZMED.REC.1399.044

Health conditions studied

1

Description of health condition studied

Postoperative peritoneal adhesion

ICD-10 code

K66.0

ICD-10 code description

Peritoneal adhesions (postprocedural) (postinfection)

Primary outcomes

1

Description

Microscopic peritoneal adhesion

Timepoint

Effect of glycerol and sodium pentaborate formulation on postoperative microscopic peritoneal adhesion

Method of measurement

Microscopic adhesion score

2

Description

Gross peritoneal adhesion

Timepoint

Effect of glycerol and sodium pentaborate formulation on postoperative gross peritoneal adhesion

Method of measurement

Gross adhesion score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Wash the peritoneal area with 100 ml of 3% glycerol and 3% sodium pentaborate at the beginning and end of surgery.

Category

Prevention

2

Description

Control group: Wash the peritoneal area with 100 ml of normal saline at the beginning and end of surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Dawood Aghamohammadi

Street address

Emam Reza hospital, Golgasht Str., Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5163995479

Phone

+98 41 3336 1928

Email

daghamohamadi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

6532985628

Phone

+98 41 3334 4280

Email

Samiei.moh@gmail.com

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

Dawood Aghamohammadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emam Reza hospital, Golgasht Str., Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5163995479

Phone

+98 41 3336 1928

Email

daghamohamadi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dawood Aghamohammadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emam Reza hospital, Golgasht Str., Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5163995479

Phone

+98 41 3336 1928

Email

daghamohamadi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dawood Aghamohammadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emam Reza hospital, Golgasht Str., Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5163995479

Phone

+98 41 3336 1928

Email

daghamohamadi@yahoo.com

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