Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of perioperative probiotic treatment on postoperative complications after colorectal surgery-a randomized clinical trial

Protocol summary

Study aim

The effects of perioperative treatment by probiotics in decreasing the complications of colorectal surgery

Design

All patients referred to surgery wards of Tabriz University of medical sciences in year 2017 for colorectal surgery are randomized between to intervention (who receives probiotic) and control group (who doesn't receive probiotic) and followed for 30 days after the operation for the complications of surgery.

Settings and conduct

Preoperative bowel preparation is done in both intervention and control group by oral polyethylene glycol, erythromycin and metronidazole and intravenous cefazolin. Cefazolin is continued for 48 hours after the operation or changed by the surgeon opinion due to intraoperative spillage. Intervention group will receive daily Familact capsule as the probiotic drug from 7 days before the operation till a total of 30 days. All patients will be followed for 30 days after the operation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: need for any elective colorectal surgery;surgery is done by an attending surgeon; good nutritional status Exclusion criteria: no consent to enter the study; small or large bowel obstruction; anticoagulant consumption; ASA class IV; inflammatory bowel disease; history of chemotherapy; transplant recipients; liver cirrhosis; antibiotic consumption in the week before surgery; steroid consumption; diabetes mellitus; pregnancy or breastfeeding; immunodeficiency of any cause

Intervention groups

Intervention group are those patients who receive probiotic drug and the control group is those who don't receive the drug.

Main outcome variables

Age; sex; duration of operation; type of surgery; first time of gas passing; tolerance of oral feeding; total hospital stay; surgical site infection; anastomosis rupture; wound dehiscence; diarrhea; pulmonary infection; urinary tract infection; sepsis; mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140203016473N9**
Registration date: **2018-05-12, 1397/02/22**
Registration timing: **retrospective**

Last update: **2018-05-12, 1397/02/22**
Update count: **0**

Registration date

2018-05-12, 1397/02/22

Registrant information

Name
Farzad Kakaei
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1334 1317
Email address
fkakaei@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-20, 1397/06/29

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

empty

Scientific title

The effects of perioperative probiotic treatment on postoperative complications after colorectal surgery-a randomized clinical trial

Public title

The effects of perioperative probiotic treatment after colorectal surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Need for any elective colorectal surgery Nurgery is done by an attending surgeon Good nutritional status

Exclusion criteria:

No consent to enter the study Small or large bowel obstruction Anticoagulant consumption ASA class IV Inflammatory bowel disease History of chemotherapy Transplant recipients Liver cirrhosis Antibiotic consumption in the week before surgery Steroid consumption Diabetes mellitus Pregnancy or breastfeeding Immunodeficiency of any cause

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomized between two study (who will receive the probiotic) and control (who will not receive the probiotic) groups by the random numbers produced by the website: www.randomizer.org

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 Tabriz University of medical sciences

Street address

Azadi Ave, Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-03-12, 1396/12/21

Ethics committee reference number

IR.TBZMED.REC.1396.1304

Health conditions studied

1

Description of health condition studied

Malignant diseases of colon

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

2

Description of health condition studied

Benign diseases of the colon, rectum, anus and anal canal

ICD-10 code

D12

ICD-10 code description

Benign neoplasm of colon, rectum, anus and anal canal

3

Description of health condition studied

Foreign body in colon

ICD-10 code

T18.4XXA

ICD-10 code description

Foreign body in colon, initial encounter

4

Description of health condition studied

Other specified diseases of intestine

ICD-10 code

K63.8

ICD-10 code description

Other specified diseases of intestine

Primary outcomes

1

Description

Anastomosis rupture
Timepoint
Daily till 30 days after the operation
Method of measurement
Physical examination

2

Description
Surgical site infection
Timepoint
Daily till 30 days after the operation
Method of measurement
Physical examination

3

Description
Fascia dehiscence
Timepoint
Daily till 30 days after the operation
Method of measurement
Physical examination

4

Description
Pulmonary infection
Timepoint
Daily till 30 days after the operation
Method of measurement
Chest x-ray if clinically indicated

5

Description
Urinary infection
Timepoint
Daily till 30 days after the operation
Method of measurement
Urinalysis if clinically indicated

6

Description
Total duration of hospital stay
Timepoint
Daily
Method of measurement
Total duration of hospital stay till discharge

7

Description
Mortality
Timepoint
Daily
Method of measurement
Report of death by attending physician

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pre- and postoperative treatment by oral probiotic drug after colorectal surgery
Category
Treatment - Drugs

2

Description
Control group: Routine pre- and postoperative treatment of colorectal surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam reza hospital
Full name of responsible person
Mohammadreza Shahrasbi
Street address
Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614695
Phone
+98 41 3334 7054
Fax
+98 41 3334 1317
Email
Mohammadrezashahrasbi@yahoo.com
Web page address
Http://imamreza.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghasem Jouyban
Street address
Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5169664339
Phone

+98 41 3335 7310

Fax

+98 51 6661 4695

Email

Ajouyban@hotmail.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

Farzad Kakaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614695

Phone

+98 41 3334 1317

Email

fkakaei@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Farzad Kakaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614695

Phone

+98 41 1334 1317

Fax

+98 41 1334 1317

Email

Fkakaei@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Farzad Kakaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5166614695

Phone

+98 413341317

Email

fkakaei@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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable