

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jul 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 Shahrashbi  
**Street address**  
Golgashat Street  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5166614695  
**Phone**  
+98 41 3334 7054  
**Fax**  
+98 41 3334 1317  
**Email**  
Mohammadrezashahrashbi@yahoo.com  
**Web page address**  
[Http://imamreza.tbzmed.ac.ir](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**  
Golgashat 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