Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of synbiotic on complications after gastrointestinal surgery - randomized clinical trial

Protocol summary

Study aim
Evaluation of the effect of synbiotics on complications after gastrointestinal surgery

Design
All patients referred to the surgical ward of Shahid Mohammadi Hospital in Bandar Abbas who need gastrointestinal surgery are divided into two intervention groups (receiving synbiotics) and the control group (receiving placebo) using a random number table. Complications of surgery in them will be examined until the day of discharge.

Settings and conduct
Patients undergoing gastrointestinal surgery will be divided into two groups, the case and the control. All patients will receive medication or placebo for another week 7 days before surgery and as soon as oral feeding begins. The drug will be prescribed 2 times a day after meals (until oral and intravenous antibiotics are taken at least 2 hours apart). The placebo group will also receive the placebo as instructed above.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patient satisfaction, need for elective gastrointestinal surgery for any reason; Existence of proper nutritional status for surgery. Exclusion criteria: Patient dissatisfaction to enter the study, patient with underlying diseases such as diabetes, coagulation disorders, congenital or acquired immunodeficiency, liver cirrhosis, renal failure, acute pancreatitis

Intervention groups
The intervention group is patients receiving the synbiotic drugs and the control group is patients receiving placebo.

Main outcome variables
postoperative ileus, number of days after hospitalization, time to start oral feeding, postoperative infection / abdominal abscess/ulcer infection, postoperative pneumonia Surgery, Anastomotic leak, Heart failure / Kidney failure / Liver dysfunction, Nausea and vomiting, pain and indigestion, Fever, Mortality 30 days after surgery, SIRS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210804052083N1**
Registration date: **2022-04-10, 1401/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-10, 1401/01/21**
Update count: **0**

Registration date
2022-04-10, 1401/01/21

Registrant information

Name
Ahmadreza Karimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 76 3373 2145

Email address
karimi.ahmadreza@hums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2022-05-20, 1401/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of synbiotic on complications after gastrointestinal surgery - randomized clinical trial

Public title
Evaluation of the effect of synbiotic on complications after gastrointestinal surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient satisfaction for inclusion in the study need for elective gastrointestinal surgery having a proper nutritional status for surgery

Exclusion criteria:
Patient dissatisfaction to enter the study patient with underlying diseases such as diabetes, coagulation disorders, congenital or acquired immunodeficiency, liver cirrhosis, renal failure, acute pancreatitis

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Before assigning groups to individuals eligible to participate in the study, informed consent is completed for grouping individuals. the person who has no role in admitting patients and assigning patients to random codes preparing random sequences using online tools (https://www.sealedenvelope.com/) and by permuted block randomization method. Individualized random allocation is done in blocks with sizes 2 and 4, and without stratification. eligibility criteria are monitored by the person responsible for admitting patients. Codes in a random sequence are assigned to patients by the treatment team without knowing that each code is in the intervention or placebo group. Patient codes are then matched to randomly generated sequence information for interventions. (randomization concealment is done by the treatment team without informing the person responsible for admitting patients and the person who prepared the random sequence.)

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, all participants are aware of participating in this study and enter the study with their consent. All participants are unaware of which group of this study they are in and after grouping patients in the groups, Patients receive synbiotic in the treatment group and receive a placebo in the control group. The lead researcher, health care personnel, data collection officials are aware of the grouping of patients. Those who prepare the draft of the article are unaware of the groupings if they do not cooperate in the above cases. The outcome assessor physician will be unaware of the patient's allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences

Street address
Jomhory Boulevard - Shahid Mohammadi Hospital

City
Bandar Abbas

Province
Hormozgan

Postal code
7919915519

Approval date
2021-06-21, 1400/03/31

Ethics committee reference number
IR.HUMS.REC.1400.117

Health conditions studied

1

Description of health condition studied
Benign neoplasms of the large intestine, rectum, anus and anal canal

ICD-10 code
D12

ICD-10 code description
Benign neoplasm of colon, rectum, anus and anal canal

2

Description of health condition studied
Benign neoplasms of other parts and obscure parts of the gastrointestinal tract

ICD-10 code
D13

ICD-10 code description
Benign neoplasm of other and ill-defined parts of digestive system

3

Description of health condition studied
Malignant mesothelial and soft tissue neoplasms
ICD-10 code
C45.1
ICD-10 code description
Mesothelioma of peritoneum

4

Description of health condition studied
Carcinoma in situ of other gastrointestinal organs and unspecified gastrointestinal organs
ICD-10 code
D01
ICD-10 code description
Carcinoma in situ of other and unspecified digestive organs

5

Description of health condition studied
Carcinoma in situ of oral cavity, oesophagus and stomach
ICD-10 code
D00
ICD-10 code description
Carcinoma in situ of oral cavity, esophagus and stomach

6

Description of health condition studied
Benign carcinoma 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

7

Description of health condition studied
Neoplasms with indeterminate or unspecified behavior of the oral cavity and gastrointestinal tract
ICD-10 code
D37
ICD-10 code description
Neoplasm of uncertain behavior of oral cavity and digestive organs

8

Description of health condition studied
Malignant neoplasms of the liver and intrahepatic bile ducts
ICD-10 code
C22
ICD-10 code description
Malignant neoplasm of liver and intrahepatic bile ducts

9

Description of health condition studied
Malignant gallbladder neoplasm
ICD-10 code
C23
ICD-10 code description
Malignant neoplasm of gallbladder

10

Description of health condition studied
Malignant neoplasms of other unknown parts of the bile duct
ICD-10 code
C24
ICD-10 code description
Malignant neoplasm of other and unspecified parts of biliary tract

Primary outcomes

1

Description
Postoperative ileus
Timepoint
From the day of operation to the day of discharge
Method of measurement
The first gas passing after surgery by day

2

Description
Number of days of hospitalization after surgery
Timepoint
From the day of operation to the day of discharge
Method of measurement
By day

3

Description
Time to start oral feeding
Timepoint
From the day of operation to the day of discharge
Method of measurement
The patient's first day of oral feeding after surgery

4

Description
Postoperative infection / Abdominal abscess / Wound infection
Timepoint
From the day of operation to the day of discharge
Method of measurement
Physical examination

5

Description
Postoperative pneumonia
Timepoint
From the day of operation to the day of discharge
Method of measurement

Clinical examination and chest radiography at the discretion of the physician

6

Description
Anastomosis leak
Timepoint
From the day of operation to the day of discharge
Method of measurement
Physical examination

7

Description
Heart failure / Kidney failure / Liver disfunction
Timepoint
From the day of operation to the day of discharge
Method of measurement
Request laboratory tests if there are clinical signs

8

Description
nausea and vomiting
Timepoint
From the day of operation to the day of discharge
Method of measurement
Clinical examination and patient complaints

9

Description
Pain and dyspepsia
Timepoint
From the day of operation to the day of discharge
Method of measurement
Clinical examination and patient complaints

10

Description
Fever
Timepoint
From the day of operation to the day of discharge
Method of measurement
Physical examination

11

Description
Mortality in 30 days after surgery
Timepoint
From the day of surgery to 30 days after surgery
Method of measurement
Death report by physician

12

Description
SIRS
Timepoint
From the day of operation to the day of discharge
Method of measurement
Request tests if there are clinical signs

Secondary outcomes

empty

Intervention groups

1

Description
Group A: In the intervention group, patients will receive lactocare capsules 500mg (zist takhmir pharmaceutical company) 7 days before surgery and as soon as they start oral administration after surgery until their discharge or for a maximum of one week. The drug will be prescribed twice a day after meals and oral or intravenous antibiotics should not be taken for at least 2 hours.
Category
Treatment - Drugs

2

Description
Group B: In the control group, patients will receive placebo capsules 7 days before surgery and as soon as they start oral administration after surgery until their discharge or for a maximum of one week. The drug will be prescribed twice a day after meals and oral or intravenous antibiotics should not be taken for at least 2 hours.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital
Full name of responsible person
Mehrdad Sayadi Nia
Street address
Islamic Republic Boulevard
City
bandar abbas
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7919915519
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+98 76 3334 7001
Email
drsaiiadinia@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas 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?
No

Title of funding source
Researcher

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Ahmadreza Karimi
Position
Medical Student
Latest degree
A Level or less
Other areas of specialty/work
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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
No - There is not 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