

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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)

Phone

+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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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teymur Aghamolai

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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

General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Mehrdad Sayadinia

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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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