Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of probiotic effect and placebo on reduction of surgical site infection after colectomy

Protocol summary

Summary

The purpose of this research is to study the effects of the Probiotics in decreasing surgical site infection after colectomy. Eighty patients above 13 years of age and with colorectal cancer, who referred to Razi, Golestan and Emam Khomeini Hospitals during two years of 1390 and 1391, were classified into two groups of "intervention" and "control" by block randomization. The following were excluded from the trial: critically ill patients, patients with central venous catheter, disrupted mucosal barrier, short bowel syndrome, abnormal cardiac valves, prosthetic valves or joints. Those patients of "intervention" group received England-made Balance Capsules; and patients of "control" group received Placebos, both of which were taken 2 doses daily in the period from four days before operation and ten days after. WBC diff, CRP, IL6, and TNF-a in the patients of both groups were checked at the beginning of the observation and 72 hours after operation. And their temperature, pulse rate, respiratory rate, and blood pressure were checked at the beginning of the research and then the first, second, third, tenth and thirtieth day after operation. Likewise, the creation of cellulitis and purulent discharge from operation area in the patients were evaluated at the first, second, third, tenth, and thirtieth day after operation. In addition to the above, mortality, the necessity for admission to ICU and the related duration were evaluated, too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304187197N7**
Registration date: **2013-05-12, 1392/02/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-12, 1392/02/22

Registrant information

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Ahwaz Jundishapur University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Ahwaz Jundishapur University of Medical Sciences

Expected recruitment start date

2012-02-04, 1390/11/15

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of probiotic effect and placebo on reduction of surgical site infection after colectomy

Public title

Evaluation of probiotic effect and placebo on reduction of surgical site infection after colectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Patients older than 13 years old with colorectal cancer that came to Razi, Emam Khomeini and Golestan hospital for colectomy between 1390-1391 Exclusion criteria: 1- critically ill patients 2- patients with central venous catheter 3- disrupted mucosal barrier 4- short bowel syndrome 5- abnormal cardiac valves 6- prosthetic valves 7- prosthetic joints

Age

From **13 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Giving the medicine to the patients was arranged in a double blind method so as to guarantee the minimum of the physician´s personal prejudgment when filling the patients' form and the maximum of the patient´s cooperation. Neither the physician nor the patients had any knowledge about the type of medicine.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwas Jundishapur University of Medical Sciences

Street address

Vice chancellor for research, Ahwaz Jundishapur University of Medical Sciences

City

Ahwaz

Postal code

Approval date

2012-01-21, 1390/11/01

Ethics committee reference number

5242//پ/8/20/د

Health conditions studied

1

Description of health condition studied

Colorectal cancer

ICD-10 code

c18.9, c19

ICD-10 code description

C18.9 Colon, unspecified, C19 Malignant neoplasm of rectosigmoid junction, C20 Malignant neoplasm of rectum, C21.0 Anus, unspecified

Primary outcomes

1

Description

surgical site infection

Timepoint

beginning of intervention and first, second, third, tenth and thirtieth days after operation

Method of measurement

fever, respiratory rate, pulse rate, pulse rate, cellulitis, dyscharge

Secondary outcomes

1

Description

WBC/diff

Timepoint

beginning of investigation and 72 hours after surgery

Method of measurement

kit

2

Description

IL6

Timepoint

beginning of investigation and 72 hours after surgery

Method of measurement

Bendermed kit

3

Description

TNF-a

Timepoint

beginning of investigation and 72 hours after surgery

Method of measurement

Bendermed kit

4

Description

CRP

Timepoint

beginning of investigation and 72 hours after surgery

Method of measurement

Roch kit

Intervention groups

1

Description
Control group: Placebo was given every 12 hours/ orally from 4 days before through 10 days after operation
Category
Treatment - Drugs

2

Description
Case group: Balance capsule made in England was given every 12 hours/ orally from 4 days before through 10 days after operation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi, Emam Khomeini and Golestan Hospital
Full name of responsible person
doctor Farzane Behmanesh
Street address
Medical Science Golestan dormitory, Ahwaz, Khoozestan
City
Ahwaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahwaz University of Medical Science
Full name of responsible person
Doctor Mostafa Feqhy
Street address
Jundishapur University, Daneshgah street.
City
Ahwaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Ahwaz University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ahwaz Jundishapur University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty