Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Probiotics for the Prevention and Treatment of Radiation-induced Diarrhea in Patients with Cancer

Protocol summary

Summary

The present study was conducted to evaluate the effects of probiotic and probiotic plus honey on radiation-induced diarrhea. Sixty-three adult patients with pelvic cancer who undergo radiotherapy for four weeks are enrolled. The presence of any acute or chronic gastrointestinal condition associated with diarrhea before recruitment and getting pelvic radiotherapy in the past are the exclusion criteria. They randomize to receive probiotic, probiotic plus honey or placebo from one week before radiotherapy for five weeks. Diarrhea grade and stool consistency are recorded weekly according to the Common Toxicity Criteria system and the Bristol scales, respectively. Also some hematological and immunological factors are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030421338N1**
Registration date: **2015-04-11, 1394/01/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-11, 1394/01/22

Registrant information

Name

Mahnaz Roayaei

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 7396

Email address

roayaei@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences.

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Probiotics for the Prevention and Treatment of Radiation-induced Diarrhea in Patients with Cancer

Public title

Effects of Probiotics on diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: Patients with pelvic cancers (colorectal, prostate, endometrial, bladder, ovary, cervical, bone sarcoma) who undergo pelvic radiotherapy. The exclusion criteria: The presence of any acute or chronic gastrointestinal condition associated with diarrhea before recruitment and getting pelvic radiotherapy in the past.

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **63**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Center of Medical Research - Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran
City
Isfahan
Postal code
81745319
Approval date
2012-10-17, 1391/07/26
Ethics committee reference number
491005

Health conditions studied

1

Description of health condition studied
Neoplasms
ICD-10 code
C17, C18,
ICD-10 code description
Malignant neoplasm of small intestine, Malignant neoplasm of colon, Malignant neoplasm of rectosigmoid junction, Malignant neoplasm of rectum

Primary outcomes

1

Description
Diarrhea grade
Timepoint
Weekly from one week before radiotherapy until end of treatment
Method of measurement
Common Toxicity Criteria system

2

Description
Stool consistency score
Timepoint
Weekly from one week before radiotherapy until end of treatment
Method of measurement
Bristol scales

3

Description
Blood cell counts
Timepoint
Weekly from one week before radiotherapy until end of treatment
Method of measurement
cell counter machine

4

Description
Serum IgA level
Timepoint
Weekly from one week before radiotherapy until end of treatment
Method of measurement
Autoanalyzer machine

Secondary outcomes

1

Description
Bloting
Timepoint
Weekly during treatment
Method of measurement
Question from the patient

Intervention groups

1

Description
group two take a combination of probiotic and honey (two probiotic capsules and 30 grams honey per day, one capsule and 15 grams honey in the morning after breakfast and another one capsule in the evening, and 15 grams honey at night)
Category
Treatment - Drugs

2

Description
group three are the control group receive two placebo capsules (containing 500 mg of corn starch) per day, one

capsule in the morning after breakfast and another one in the evening

Category

Treatment - Drugs

3

Description

group one take probiotics)contained: Lactobacillus casei 1.5 × 109 CFU, Lactobacillus acidophilus 1.5 × 1010 CFU, Lactobacillus rhamnosus 3.5 × 109 CFU, Lactobacillus bulgaricus 2.5 × 108 CFU, Bifidobacterium breve 1 × 1010 CFU, Bifidobacterium longum 5 × 108 CFU and Streptococcus thermophilus 1.5 × 108 CFU per 500 mg(; two probiotic capsules per day, one capsule in the morning after breakfast and another one in the evening

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyed-Al-Shohada Hospital

Full name of responsible person

Dr. Mahnaz Roayaei

Street address

Sayyed-Al-Shohada Hospital, Motahari Street, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Hadi Toghiany

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan. ran

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of Medical Sciences

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

University of Isfahan

Full name of responsible person

Hajar-Alsadat Mansouri-Tehrani

Position

MSc in Biotechnology

Other areas of specialty/work

Street address

Hezar Jarib Street

City

Isfahan

Postal code

Phone

+98 31 3273 2059

Fax

+98 31 3273 2188

Email

hajar_mansouri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mahnaz Roayaei

Position

Assistant Professor / PhD in Radiotherapist

Other areas of specialty/work

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31 3776 7396

Fax

Email

Roayaei@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

University of Isfahan

Full name of responsible person

Hajar-Alsadat Mansouri-Tehrani

Position

MSc in Biothecnology

Other areas of specialty/work
Street address
University of Isfahan, Hezar Jarib Street, Isfahan, Iran
City
Isfahan
Postal code
Phone
+98 31 3273 2059
Fax
Email
hajar_mansouri@yahoo.com
Web page address

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