Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of probiotics on the prevention of diarrhea in two groups of patients treated with antibiotics and patients treated with antibiotics and probiotics

Protocol summary

Study aim

The effect of probiotics in preventing diarrhea caused by antibiotics

Design

Clinical trials with 2 groups of 150 parallel,with controlled group, single blind, randomized by random numbers

Settings and conduct

The study will be done as a single-blind form. 300 patients aged between 18-94 years old who were referred to infectious clinics of Sina and Imam Reza Hospital and Sheikh Al-Reyes Clinic in Tabriz from 4.4.2017 to 3.6.2018 and need to be treated with antibiotics for any reason, will be selected and informed upon completion of informed consent form. Samples are divided into groups of Intervention and Placebo by randome numbers and will take medication or placebo. Patients are advised blind about taking the medication or placebo, and they will not know the contents of the pack (medication or placebo). The Probiotic drug used in this design is a capsule containing Saccharomyces cerevisiae brand Yomogi 250 mg. In the control group, 250 mg of lactose-free dry milk will be used in capsules similar to the Probiotic.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- The age range is 18-94 years 2- Receiving antibiotics for any cause 3. Informed consent of Patients to Participate in the Study. Exclusion criteria: 1- Patients with diarrhea at home 2- Patients with any pathological illness that causes diarrhea 3- History of intestinal surgery 4- Rheumatism and endocarditis 5- Patients treated with laxative 6- Antibiotic use over the past 2 weeks 7- Patients with artificial valve and immune deficiency

Intervention groups

All patients who have been referred to the infectious clinics of Sina and Imam Reza hospitals and Shaikh-e-Reyes Clinic of Tabriz from 4.4.2017 to 3.6.2018 are treated with antibiotics for any reason.They were divided into two groups. They receive an antibiotic and a group of antibiotics and probiotics.

Main outcome variables

Diarrhea; colitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180805040711N1**
Registration date: **2018-09-15, 1397/06/24**
Registration timing: **retrospective**

Last update: **2018-09-15, 1397/06/24**
Update count: **0**

Registration date

2018-09-15, 1397/06/24

Registrant information

Name

Seyyed Mehdi Haghdoost

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 5411

Email address

haghdustm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date
2017-04-04, 1396/01/15
Actual recruitment end date
2018-03-06, 1396/12/15
Trial completion date
empty

Scientific title
Comparison of the effect of probiotics on the prevention of diarrhea in two groups of patients treated with antibiotics and patients treated with antibiotics and probiotics

Public title
The effect of Probiotics in the prevention of diarrhea caused by antibiotics
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
The age range is 18-94 years Need to get antibiotics for any cause Conscious Consciousness of Patients to Participate in the Study
Exclusion criteria:
Patients with diarrhea at the time of admission Patients with any pathological illness that causes diarrhea History of intestinal surgery Rheumatism and endocarditis Patients treated with laxative Patients who have had antibiotic use in the last 2 weeks Patients with artificial valve and immune deficiency
Age
From **18 years** old to **94 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **300**
Actual sample size reached: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method will be simple random. The samples will be randomly divided by random numbers into two groups of intervention group and placebo group (150 in each group).
Blinding (investigator's opinion)
Single blinded
Blinding description
The study will be done as a single-blind form. The Probiotic drug used in this design is a capsule containing Saccharomyces Cerevisiae brand Yomogi 250 mg. In the control group, 250 mg of lactose-free dry milk will be used in capsules similar to the Probiotic capsules. Capsules will be packaged and coded. Samples are divided into groups of intervention group and placebo group by random numbers. Patients are blinded about taking the medication or placebo, and they will not know the contents of the pack (medication or placebo).
Placebo
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 Science (Human Subjects Studies)
Street address
Gholghasht Ave, Tabriz City
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2018-07-23, 1397/05/01
Ethics committee reference number
IR.TBZMED.REC.1397.359

Health conditions studied

1

Description of health condition studied
Diarrhea caused by antibiotics
ICD-10 code
K59.1
ICD-10 code description
Functional diarrhea

Primary outcomes

1

Description
The volume and frequency of antibiotic-induced diarrhea
Timepoint
The beginning of the treatment (before the intervention), during and two weeks after treatment
Method of measurement
Checklist designed in the study (The frequency of diarrhea is over 3 times and the volume of diarrhea is about 200 grams per day)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The Probiotic drug capsule containing Saccharomyces cerevisiae brand Yomogi 250 mg
Category
Prevention

2

Description
Control group: 250 mg of lactose-free dry milk will be used in capsules similar to the Probiotic capsule
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Dr.Seyed Mehdi Haghdoost
Street address
Gholghasht Ave, Tabriz City
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Tabriz
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Postal code
5166615745
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+98 41 3334 7056
Email
info@imamreza.tbzmed.ac.ir
Web page address

2

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Dr.Seyed Mehdi Haghdoost
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Azadi Ave, Tabriz City
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+98 41 3549 8140
Email
info@sinahosp.tbzmed.ac.ir

3

Recruitment center
Name of recruitment center
Sheikholraies clinic
Full name of responsible person
Dr.Seyed Mehdi Hghdoost
Street address
Azadi Ave, Tabriz City
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info@shaclinic.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Abolghasem Jouyban
Street address
Tabriz Univercity of Medical Science,Daneshghah Street, Tabriz City
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Email
Ajouyban@hotmail.com
Web page address
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
Dr.Seyed Mehdi Haghdoost
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Medicine Faculity, Ghoghasht Ave, Tabriz City
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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
Undecided - It is not yet known if there will be 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