

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of using probiotic yogurt in preventing antibiotic- associated diarrhea

Protocol summary

Study aim

Determination of the effects of probiotic yogurt in preventing diarrhea caused by antibiotics in hospitalized patients

Design

In this study, 50 patients with suspected diarrhea following antibiotic use will be entered in the 3rd phase of clinical trial. Participants will be placed in control and intervention groups. Each participant is assigned a code.

Settings and conduct

This study is done Double-blind. Participants and researchers are blind in this study. Participants included patients referring to Ghaem Hospital. Intervention group taking probiotic yogurt, contains lactobacillus and the control group taking normal yogurt . The effects of consumption of yogurt in these two groups are studied and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: antibiotic use and patient satisfaction
Exclusion criteria: 1. Severe respiratory infection (severe pneumonia) that the patient should be an NPO 2 - Gastrointestinal diseases such as gastroenteritis and evidence of infectious diarrhea associated with clinical symptoms of fever, accompanied by vomiting and bloody diarrhea

Intervention groups

Control group: control group is given The usual yogurt.
Intervention group: The subjects in the intervention group are given probiotic yogurt containing lactobacillus which will be followed up to 2 weeks after the start of concurrent administration of antibiotics and probiotics.

Main outcome variables

The duration of diarrhea Frequency of bowel movements
Consistency of stool

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101107005123N2**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **retrospective**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

Hamidreza Kianifar

Name of organization / entity

Mashahd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1801 2469

Email address

kianifarhr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

2013-02-19, 1391/12/01

Actual recruitment end date

2014-02-20, 1392/12/01

Trial completion date

empty

Scientific title

The effects of using probiotic yogurt in preventing antibiotic- associated diarrhea

Public title

The Effect of Probiotic Yogurt in Preventing Diarrhea

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Taking antibiotics patients satisfaction

Exclusion criteria:

Severe respiratory tract infections (severe pneumonia) that the patient should have NPO. Gastrointestinal diseases such as gastroenteritis and evidence of infectious diarrhea associated with clinical symptoms of fever and associated with vomiting and bloody diarrhea

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random number table, participants will be randomized in two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the project, the participants, as well as the researcher who tracks the patients, are unaware of which group they are and the only one who is aware is the analyzer.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Daneshgah Ave, Ghoreishi buildings

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Approval date

2014-06-11, 1393/03/21

Ethics committee reference number

IR.MUMS.REC.1393.104

Health conditions studied**1****Description of health condition studied**

antibiotic- associated diarrhea

ICD-10 code

(A00-B99)

ICD-10 code description

Certain infectious and parasitic diseases

Primary outcomes**1****Description**

Duration of diarrhea

Timepoint

Before the intervention and 2 weeks later

Method of measurement

Questionnaire

2**Description**

Frequency of bowel movements

Timepoint

Before the intervention and 2 weeks later

Method of measurement

Questionnaire

3**Description**

Consistency of stool

Timepoint

Before the intervention and 2 weeks later

Method of measurement

Based on the quality of the stool

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: This group includes 50 people who take regular yogurt for 2 weeks.

Category

Treatment - Other

2

Description

Intervention group: This group includes 50 people who take probiotic yogurt for 2 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Dr Ali Jafari

Street address

Ghaem Hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3801 2297

Email

jafaria@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Daneshgah AVE, Ghoreishi Buildings

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3821 2081

Email

ramresearch@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Ahmad abad Ave, Ghaem Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3801 2297

Email

jafaria@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Hamid reza Kianifar

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics Gastroenterologist

Street address

Fakoori Ave, Akbar Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3801 2297

Email

kianifarhr@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Kianifar

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics Gastroenterologist

Street address

Fakoori Ave, Akbar Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3801 2297

Email

Kianifarhr@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The work has not been completed and the study may continue

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable