

# 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

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**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

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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

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**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

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Fakoori Ave, Akbar Hospital

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**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

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## 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