

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of probiotic yogurt on the prevalence of Clostridium difficile infections in patients hospitalized in arak Vali Asr Hospital

Protocol summary

Summary

Clostridium difficile is the most common cause of antibiotic-associated diarrhea (AAD) and antibiotic associated colitis (AAC) in the hospital setting. In this study, the prophylactic effect of probiotic yogurt was investigated on AAC. In this double blind randomized clinical trial study, 132 patients according to our inclusion and exclusion criteria were enrolled to the study and randomly divided into two groups, case (yogurt probiotic, 200mg/day/8 day) and control group (common yogurt). All patients were trained about the signs of colitis. Colitis signs and presence of Clostridium difficile by PCR were recorded and compared between groups. Data were analyzed with appropriate statistical tests and using version 16 of SPSS statistical software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092229915N1**

Registration date: **2016-10-11, 1395/07/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-11, 1395/07/20

Registrant information

Name

Elahe Eghbal

Name of organization / entity

Ministry of Health and Educational Medical Arak

University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 4317 3503

Email address

e.eghbal@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of probiotic yogurt on the prevalence of Clostridium difficile infections in patients hospitalized in arak Vali Asr Hospital

Public title

Evaluation of probiotic yogurt on the prevalence of Clostridium difficile infections

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: persons older than 65 years old admitted in infectious diseases ward who receive antibiotics; no taking antibiotics in the past two months; signed informed consent to participate; no HIV/AIDS; absence of diarrhea during hospitalization. Exclusion criteria: the patient's unwillingness or inability to enforce orders for the study; discharge before 7 days; need for admission in ICU.

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Payambar Azam Complex

City

Arak

Postal code

3848176941

Approval date

2014-07-14, 1393/04/23

Ethics committee reference number

10-165-93

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

Clostridium Difficile infections

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Clostridium Difficile

Timepoint

8 days (during intervention)

Method of measurement

PCR method

Secondary outcomes

empty

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

Intervention group: yoghurt probiotic, 200mg/day/8 day

Category

Treatment - Other

2**Description**

Control group: common yughurt, 200mg/day/8 day

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arak Vali Asr Hospital

Full name of responsible person

Elahe Eghbal

Street address

Arak Vali Asr Hospital, Vali Asr Squ.

City

Arak

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohammad Rafiei

Street address

Arak University of Medical Sciences, Payambar Azam Complex

City

Arak

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Elahe Eghbal

Position

Resident Infectious Diseases

Other areas of specialty/work

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Position

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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