

# 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**

**Street address**

arak University of Medical Sciences, Payambar Azam  
Complex

**City**

Arak

**Postal code**

3848176941

**Phone**

+98 86 3417 3638

**Fax**

**Email**

Rsearch@arakmu.ac.ir

**Web page address**

**Phone**

+98 86 3417 3638

**Fax**

+98 86 3417 3639

**Email**

e.eghbal@arakmu.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Elahe Eghbal

**Position**

Resident Infectious Diseases

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**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

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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*