

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of probiotic *Lactobacillus* to prevent diarrhea caused by antibiotics

Protocol summary

Summary

Clostridium difficile is the main cause of diarrhea caused by antibiotics in the hospital system and the aim of this study is to evaluate the role of probiotics in prevention of diarrhea caused by antibiotics. Plan: this is a double-blind case-control study on 300 hospitalized patients who were treated with antibiotic therapy. Methods and Interventions: Patients who needed to receive antibiotics in hospital randomly divide in two case and control groups. Case group will receive two tablets solution containing 150 million spores of *Lactobacillus* by oral gavage every 12 hours, simultaneously with antibiotics. Patients will receive probiotics during the course of antibiotic therapy and one week after it is cut off. 100 grams of lactose-free milk will gavage two times a day for control group. Inclusion criteria include all patients who need antibiotic therapy in their hospital admission, and exclusion criteria include patients who are initially hospitalized with diarrhea, patients taking antibiotics 4 weeks before admission, patients with neutropenia, patients who had bowel surgery, and patients who have artificial heart valve, or endocarditis. Diarrhea is the primary outcome of this study which is evaluated at the start of the study, in the course of antibiotic therapy and completion of antibiotic treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107166056N2**

Registration date: **2011-09-22, 1390/06/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-22, 1390/06/31

Registrant information

Name

Nader Zarinfar

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2011-02-20, 1389/12/01

Expected recruitment end date

2011-08-22, 1390/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of probiotic *Lactobacillus* to prevent diarrhea caused by antibiotics

Public title

Use of probiotics to prevent diarrhea caused by antibiotics

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients who need to receive antibiotics during hospitalization. Exclusion criteria: Patients initially admitted with diarrhea, patients taking antibiotics 4 weeks before admission. Patients with

neutropenia. Patients who had bowel surgery. Patients who have artificial heart valves, or endocarditis.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 300

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 Science

Street address

Arak, Alamalhoda ave, Arak University of Medical Sciences

City

Arak

Postal code**Approval date**

2011-02-07, 1389/11/18

Ethics committee reference number

89-99-3

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

diarrhoea

ICD-10 code

K59.1

ICD-10 code description

Functional diarrhoea

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

diarrhea

Timepoint

at the start of the study, in the course of antibiotic therapy and completion of antibiotic treatment

Method of measurement

Clinical evaluation

Secondary outcomes**1****Description**

Colitis

Timepoint

at the start of the study, in the course of antibiotic therapy and completion of antibiotic treatment

Method of measurement

Clinical evaluation

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

Case group will receive two tablets solution containing 150 million spores of Lactobacillus by oral gavage every 12 hours, simultaneously with antibiotics.

Category

Treatment - Drugs

2**Description**

100 grams of lactose-free milk will gavage two times a day for control group.

Category

Placebo

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

Valie-Asr Hospital

Full name of responsible person

Dr nader zarinfar

Street address

Valie-Asr Hospital , Pirozi Ave, Arak

City

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2**Recruitment center****Name of recruitment center**

Amiralmomenin hospital

Full name of responsible person

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Amiralmomenin hospital, Basij Square, Arak

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Nader Zarinfar

Position

Assistant professor, Infectious disease specialist

Other areas of specialty/work**Street address**

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

Arak University of Medical Sciences

Full name of responsible person

Dr. Davoud Hekmatpou

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Arak University of Medical Sciences , Basij
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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

Dr Nader Zarinfar

Position

Infectious disease specialist, Assistant professor

Other areas of specialty/work**Street address**

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Position

Assistant professor, Infectious disease specialist

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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