

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the probiotic,s(lactofem) efficacy and complication on acute non complicated cystitis infection among women of reproductive age

Protocol summary

Study aim

Comparison of the incidence of bloating and indigestion in the two groups

Design

This study is a parallel double-blind clinical trial in which patients will be randomly divided into case (probiotic) and control (placebo) groups.

Settings and conduct

The study population is patients referred to the clinics of Golestan and Imam Khomeini hospitals in 1399.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All premenopausal women referring to UTI over the age of 18 who are willing to participate in the study will be included in the study. The following patients are excluded from the study: 1- Patients who have needed long-term prophylactic antibiotics due to recurrent urinary tract infections in the last 6 months. 2- Patients who have a urinary catheter

Intervention groups

Probiotic intervention will be prescribed for the intervention group and placebo for the control group

Main outcome variables

UTI recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201005048943N1**

Registration date: **2020-12-11, 1399/09/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-11, 1399/09/21**

Update count: **0**

Registration date

2020-12-11, 1399/09/21

Registrant information

Name

Narjes Yazdi baghban zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4224 5671

Email address

ybnarges@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the probiotic,s(lactofem) efficacy and complication on acute non complicated cystitis infection among women of reproductive age

Public title

Probiotics (lactofem) in the prevention of recurrence of infection in acute uncomplicated cystitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All premenopausal women with UTI Satisfaction to participate in the study

Exclusion criteria:

Patients who have needed long-term prophylactic

antibiotics due to recurrent urinary tract infections in the last 6 months. Patients who have a urinary catheter

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into case and control groups. Random function of Excel software based on patient file number will be used for randomization. Patients with uncomplicated acute cystitis were included in the Excel program based on the file number and were divided into case and control groups based on the random button. A total of two groups of 24 people were divided. By entering the file number in Excel program, then the random number is selected from the data analysis command. This study has 2 groups that can be numbered from 1 to 2, respectively. We also want to have 24 people in each group. As a result, sequences 1 to 2 should be repeated 24 times each time. It is clear that the repetition of each number occurs once in each group, so select 1 for repeating each number and 24 for repeating the sequence. In this way, 48 units will be produced. Which patient is included in which group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the clinical caregiver knows which patients are in the case group and should be prescribed probiotics, and for which group placebo is required.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Esfand St., Shahr-e-Daneshgahi, Golestan Blvd.,

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Approval date

2020-05-16, 1399/02/27

Ethics committee reference number

IR.AJUMS.REC.1399.189

Health conditions studied

1

Description of health condition studied

Acute uncomplicated cystitis

ICD-10 code

N30.0

ICD-10 code description

Acute cystitis

Primary outcomes

1

Description

Reduce relapse

Timepoint

At the beginning of the study and at the end of each month, patients will be visited during the study period.

Method of measurement

Ask the patient about changes in the patient as well as urinary symptoms and gastrointestinal complications

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The probiotic lactofem made by the bio-fermentation company starts at the rate of one per day. The drug is administered in the afternoon and 5 hours after lunch with a glass of cold water.

Category

Treatment - Drugs

2

Description

Control group: A placebo that is similar in appearance (color-shape) to the original drug is prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Shokouh Shayanpour

Street address

Farvardin Street, Golestan

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2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Shokouh Shayanpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

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

No

Title of funding source

does not have

Proportion provided by this source

1

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

Ahvaz University of Medical Sciences

Full name of responsible person

Shokouh Shayanpour

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Nephrology

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Person responsible for scientific inquiries

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Position

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Latest degree

Subspecialist

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Nephrology

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Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Narges Yazdi Baghbanzadeh

Position

Student of Medical Science

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Ahvaz Jundishapur University of Medical Sciences,
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City**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available