

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of lactofem capsule on the treatment of bacterial vaginosis in pregnant women

Protocol summary

Study aim

Determining the effect of lactofem capsule on the treatment of bacterial vaginosis

Design

This study will be performed as a triple-blind randomized clinical trial on 72 eligible pregnant women. Pregnant mothers will be divided into two groups based on stratified random sampling method and table of random numbers, in which for numbers zero to 4 in random numbers table, AB sequence and for numbers 5 to 9, BA sequence will be selected.

Settings and conduct

The present study will be performed in the gynecology clinic of Asali Hospital in Khorramabad. People in the intervention group will be given one lactofem capsule daily for one month, and in the control group, placebo will be used according to the same instructions. The study will be triple-blind and patients, researcher and statistical analyst will be unaware of patients' intervention group.

Participants/Inclusion and exclusion criteria

Inclusion requirements: Gestational age over 12 weeks, Bacterial vaginosis infection. Exclusion requirements: Concomitant infection with Trichomonas or candidiasis; Gestational diabetes, Simultaneous urinary tract infection, Rupture of amniotic membrane, Immune system defects, Inflammatory bowel disease.

Intervention groups

Intervention group (lactofem capsule): pregnant women will receive one lactofem capsule orally daily for one month. Control group (placebo): patients will receive placebo, a capsule completely similar to the main drug form. In order to prevent the ethical consideration about control group deprivation, intervention and control groups both will receive routine treatment.

Main outcome variables

Infection status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090701002114N7**

Registration date: **2020-11-16, 1399/08/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-16, 1399/08/26**

Update count: **0**

Registration date

2020-11-16, 1399/08/26

Registrant information

Name

Fatemeh Yari

Name of organization / entity

Lorestan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 1222 6450

Email address

yari.f@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-14, 1399/08/24

Expected recruitment end date

2021-01-13, 1399/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lactofem capsule on the treatment of bacterial vaginosis in pregnant women

Public title

The effect of lactofem on the vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age over 12 weeks Bacterial vaginosis infection

Exclusion criteria:

Concomitant infection with Trichomonas or candidiasis Gestational diabetes urinary tract infection Rupture of the amniotic sac Immune system defects Inflammatory bowel disease

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be randomly assigned to the study after visiting the gynecology clinic. Randomization will be in the form of blocking in such a way that the method of replacement blocks is used within each floor. The blocks will be binary, consisting of AB and BA. The randomization tool will be a table of random numbers, that using the sequence AB for numbers zero through 4 in the random number table and the sequence BA for 5 to 9. It should be noted that the letter A means the intervention group and the letter B means the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be a three-way blind and the patient, researcher and statistical analyst of the patients' group therapy have no information and the decoder is outside the research team. The drug under study (lactofem) and placebo in a completely similar shape and appearance, each of which is 30 in the same bottle instead of the drug will be provided to the subjects based on random allocation. It should be noted that the drug content of each The bottles are code-tagged on the bottles by the pharmacist consultant and the research team is not aware of their interpretation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Lorestan University of Medical Sciences

Street address

Office of Research Ethics Committee, Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences, University Campus Complex, km 3 of Khorramabad Boroujerd Road, Khorramabad

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2019-03-05, 1397/12/14

Ethics committee reference number

IR.LUMS.REC.1397.132

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

Bacterial vaginosis infection

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

Bacterial vaginosis

Timepoint

Evaluation of vaginal infection at the beginning of the study and one month after taking Lactofem capsules

Method of measurement

Vaginal examination by physician

Secondary outcomes

empty

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

Intervention group: pregnant women who have a bacterial vaginosis infection according to a doctor's

examination will be treated with Lactofem oral capsules and will take one capsule daily for one month. After a month, they will be examined by a doctor.

Category

Treatment - Drugs

2**Description**

Control group: In this group, instead of lactofem capsule, a placebo capsule with a similar shape and appearance will be used. Placebo will be used daily for a month. After a month, they will be examined by a doctor.

Category

Placebo

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

Asalian Hospital

Full name of responsible person

Dr. Masoumeh Ghaffarzadeh

Street address

Asalian Hospital,14th Street, Palestine Alley

City

Khorramabad

Province

Lorestan

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6818795895

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+98 66 3340 6099

Email

asali.hospital@lums.ac.ir

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Ibrahim Fallahi

Street address

Medical school, 4 km Khorramabad Boroujerd Road,
Kamalvand

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Province

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Email

falahi.e@lums.ac.ir

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

Yes

Title of funding source

Khoram-Abad 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**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Fatemeh Yari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Medical school.,4 km Khorramabad Boroujerd
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Fatemeh Yari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences
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Fatemeh Yari
Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

It is possible to share all the data while maintaining the principle of not mentioning the names of individuals

When the data will become available and for how long

One year after the publication of the related article

To whom data/document is available

Researchers of university centers

Under which criteria data/document could be used

For additional research and production of probiotic therapeutic compounds, the data of the present study can be used after obtaining permission and approval from the Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences

From where data/document is obtainable

Refer to the project manager, Dr. Fatemeh Yari, with email address yari1672@yahoo.com, and contact number 09163613621

What processes are involved for a request to access data/document

After completing the research and publishing the relevant article, individuals can apply to the Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences to receive documents and after obtaining permission from this department, send a confirmation from the Vice Chancellor for Research to the project manager. Can access documentation.

Comments