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 willreceive 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 committe 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

Postal code

6818795895

Phone

+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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Phone

+98 66 3312 0172

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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

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Medical school.,4 km Khorramabad Boroujerd Road.,Kamalvand

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

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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