

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of lactic acid-containing vaginal cream in the treatment of dryness, burning and vaginal infection in women

Protocol summary

Study aim

The effect of lactic acid-containing vaginal cream in the treatment of dryness, burning and vaginal infection in women

Design

Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 3 on 240 patients. The random function of Excel software was used for randomization.

Settings and conduct

Authorized obstetrics and gynecology clinics in Khorramabad

Participants/Inclusion and exclusion criteria

Married women aged 18-70 who are not pregnant, breastfeeding or menopausal. They also do not have vaginal bleeding and have not used a vaginal cream or suppository in the last 48 hours

Intervention groups

Placebo group: A group that receives a placebo. Group therapy: A group that receives medication. Participants and obstetricians had no knowledge of placebo or treatment and were randomly given medication or placebo, and at the end it was determined who was in the placebo group and who was in the treatment group.

Main outcome variables

Vaginal itching, Vaginal burning, Vaginal moisture, The amount of vaginal discharge, Vaginal discharge color, Pain during intercourse, Abnormal vaginal bleeding or spotting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210810052135N1**

Registration date: **2022-05-05, 1401/02/15**

Registration timing: **prospective**

Last update: **2022-05-05, 1401/02/15**

Update count: **0**

Registration date

2022-05-05, 1401/02/15

Registrant information

Name

Amin Hasanvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3312 0133

Email address

dr.hasanvand@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lactic acid-containing vaginal cream in the treatment of dryness, burning and vaginal infection in women

Public title

Evaluation of the effect of lactic acid in the treatment of dryness, burning and vaginal infections

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women aged 18-70 who are not pregnant, breastfeeding or menopausal. The sample population did not have vaginal bleeding and had not used a vaginal cream or suppository in the past 48 hours. The sample population has not used antibiotics or antifungals to treat vaginitis in the last 2 weeks. The specimens should not have used corticosteroids in the past 2 weeks.

Exclusion criteria:

Existence of other infections associated with candidiasis
Presence of certain diseases in the samples

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

In lactic acid and clindamazole intervention, 120 samples were selected using stratified random block method in two groups (60 people in each group) and in lactic acid and estrogen intervention, 120 people (60 people in each group). Are placed in such a way that the menopausal status (postmenopausal and non-menopausal women) is first considered as a class. Then, in the samples of postmenopausal and non-menopausal women, the samples will be randomly assigned to the two groups using 4 random blocks. This method is used to avoid significant imbalances in the number of participants assigned to each group. Block randomization ensures that no significant imbalance is established between groups at any time during randomization, and at certain points the number of participants in each group is equal. For this method, the volume of each block must first be specified (Example of a quadruple block). Then write a list of blocks and assign numbers to them (AABB (1) - ABAB (2) - ABBA (3) - BBAA (4) - BABA (5) - BAAB (6)) Then select random numbers from one to 6 (Eg 1 4 5 and ...) and finally specify the treatment allocation list based on random random numbers (... AABB-BBAA-BABA-).

Participants are placed in different classes based on pre-selected factors and factors and randomization is done in each category. Randomization in each class can be simple randomization or block randomization. The advantage of this method is the comparability of groups based on specific factors. Random samples are a subset of data selected from a larger data set, our population. Each individual is selected from a random sample completely randomly, and the probability of equal selection in this case is equal, and in principle, to obtain a non-biased representation of the whole population. The letters inside the blocks (A and B) also indicate the

patient's type.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This clinical trial is three-way blind. 1. Participants in research who are patients, 2. Researchers or implementers of the project 3. People who analyze the obtained data. In this study, blindness is such that there is an external observer in these studies who assigns a common name to drugs (intervention) and placebo (control) such as: A and B. The participant / researcher / statistical consultant knows who is in group A and who is in group B. But neither knows if group A is an intervention or a control. Finally, after studying and interpreting the results by the statistician, the observer reveals what group each name belonged to.

Placebo

Not 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

Kamalvand Pardis

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2022-04-05, 1401/01/16

Ethics committee reference number

IR.LUMS.REC.1401.002

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

Vaginal dryness and burning and infections

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

Vaginal dryness and burning and infections

Timepoint

The first day and the fourteenth day

Method of measurement

questionnaire

Secondary outcomes

empty

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

Interference group:1. Estromarin-containing vaginal cream (for patients with irritation and vaginal dryness)Clindamazole vaginal cream (for patients with vaginal infection)These drugs contain an applicator for intravaginal use, which is provided to patients after two sessions of training on how, when and how much to take. At the end, a contact number will be given to answer patients' questions about any questions.

Category

Treatment - Drugs

2**Description**

Intervention group:1. Lactic acid vaginal cream (for patients with irritation and dryness and/or vaginal infections)These drugs contain an applicator for intravaginal use, which is provided to patients after two sessions of training on how, when and how much to take. At the end, a contact number will be given to answer patients' questions about any questions.

Category

Treatment - Drugs

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

Asali Hospital and Private Clinics

Full name of responsible person

Amin Hasanvand

Street address

Ghaziabad -

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3340 6099

Fax

+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

Dr. Bahram Rasoulia

Street address

Kamalvand

City

khorrarnabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3312 0172

Fax

+98 66 3312 0173

Email

research@lums.ac.ir

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

No

Title of funding source

Lorestan 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

Amin Hasanvand

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

kamalvand

City

Khorramabad

Province

Lorestan

Postal code

381251698

Phone

0986633120172

Email

dr.hasanvand@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Amin Hasanvand

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Kamalvand

City

Khorramabad

Province

Lorestan

Postal code

381251698

Phone

+98 66 3312 0172

Email

dr.hasanvand@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Amin Hasanvand

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Medicine - Lorestan university of medical science - Kamalvand

City

Khorramabad

Province

Lorestan

Postal code

381251698

Phone

+98 66 3312 0133

Fax

+98 66 3312 0133

Email

dr.hasanvand@yahoo.com

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

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

Clinical Study Report

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information on the main implications is available through the article.

When the data will become available and for how long

The access period starts one year after the results are published.

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Data analysis is allowed but the right to use the documents is not allowed.

From where data/document is obtainable

Applicants can contact the project manager via email to receive data.

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

The applicant must first submit your application. If the request is approved, he / she will sign an undertaking form not to use it industrially and provide it to others, and then the data will be sent to them.

Comments