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

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Iran (Islamic Republic of)

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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

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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 drynessClindamazole 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
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Sponsors / Funding sources

1

Sponsor
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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
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
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Full name of responsible person
Amin Hasanvand
Position
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Other areas of specialty/work
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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
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