

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Determining and comparing the effect of Clotrimazole vaginal cream and Prongus Fluorase vaginal cream (Jashir plant) on candidal vulvovaginitis

Protocol summary

Study aim

Determining the effect of Prongus Fluorase vaginal cream on candidal vulvovaginitis Comparison of Clotrimazole vaginal cream and Prongus Fluorase vaginal cream on candidal vulvovaginitis

Design

A clinical trial with a control group with a parallel group, three-blind, randomized on 112 patients, the randomization function of Excel

Settings and conduct

The vulvovaginal symptoms form in Women's clinic is completed, the mental symptoms of the vulvar and vagina such as itching, burning, and dyspareunia are determined by the client on a 10 cm visual analog scale, and the objective symptoms are recorded in the checklist according to the examiner's observations and the scoring system. Sobel placement is graded. Determining the severity and classification of candidal vulvovaginitis is done through the total score of objective and subjective symptoms in the Sobel clinical scoring system. Total Sobel score greater than 4 is considered as a possible diagnosis of candidal vulvovaginitis, then using three swabs, one of the swabs is drawn on the slide and a drop of normal xylene is added and the prepared wet slide is examined, and the second swab is examined for fungal elements, potassium hydroxide is added. The researcher, the statistical analyst and the patient are blinded

Participants/Inclusion and exclusion criteria

Entry conditions: women of reproductive age, being married, having at least two symptoms of cheesy secretions and itching and a minimum Sobel score of 4 or a positive culture. No entry: lactating women, postmenopausal women, pregnant women, suffering from diabetes, history of allergy to jashir, history of allergy to clotrimazole vaginal cream.

Intervention groups

Intervention group: Jashir vaginal cream Control group: clotrimazole vaginal cream for one week, one 5 mg applicator

Main outcome variables

Direct observation of the vagina, vaginal pH, wet vaginal smear, culture of vaginal secretions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230521058245N1**

Registration date: **2023-06-27, 1402/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-27, 1402/04/06**

Update count: **0**

Registration date

2023-06-27, 1402/04/06

Registrant information

Name

Leila Ghayashi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-25, 1402/04/04

Expected recruitment end date

2023-12-25, 1402/10/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Determining and comparing the effect of Clotrimazole vaginal cream and Prongus Fluorase vaginal cream (Jashir plant) on candidal vulvovaginitis

Public title
Determining and comparing the effect of Clotrimazole vaginal cream and vaginal cream (Jashir plant) on candidal vulvovaginitis

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
 Women of reproductive age (15 to 45 years) Being married Having at least two symptoms of cheesy secretions and itching Least a Sobel score of 4 Positive culture
Exclusion criteria:
 Failure to participate in the study Lactating women Menopausal women Menstruation Pregnant women Having diabetes Women with immunodeficiency and immunosuppressive diseases Suffering from other vaginal infections and sexually transmitted infections Frequent and recurring candidal vulginitis History of allergy to Jashir

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
0

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
For sampling, the available sample method is used, then the research units are placed in two parallel groups by a simple random allocation method using a table of random numbers. 56 women are in clotrimazole vaginal cream users group and 56 women are in Jashir vaginal cream group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
All people, including the researcher, the patient and the statistical analyst, are blinded to the drug allocation. The pharmacist will perform drug blinding. In order to blind Clotrimazole 1% cream made by a pharmaceutical company, under sterile conditions, it is emptied by the pharmacist into tubes similar to Jashir's vaginal cream

tubes, then in order to differentiate the two drugs, they are coded as A and B codes by the pharmacist for each Vaginal cream is determined and after the study and statistical analysis, the code of each drug is stated by the pharmacist. The research team includes a gynecologist, a pharmacist and a midwife

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Yasouj University of Medical Sciences
Street address
 No 402, Beach Park towards Imam Sajjad Hospital,Yasouj ,Kohgiluyeh and Boyerahmad province
City
 Yasouj
Province
 Kohgilouyeh-va-Boyerahmad
Postal code
 7591741417
Approval date
 2023-04-19, 1402/01/30
Ethics committee reference number
 IR.YUMS.REC.1402.030

Health conditions studied

1

Description of health condition studied
Candidal vulvovaginitis

ICD-10 code
B37.3

ICD-10 code description
Candidiasis of vulva and vagina

Primary outcomes

1

Description
Although vaginitis is a candidate

Timepoint
Before the start of the intervention and 7 days after the end of the intervention

Method of measurement
The score obtained from Sobel clinical semi-quantitative system

2

Description

Dysparonychia due to candidal vulvovaginitis

Timepoint

Dysparonychia due to candidal vulvovaginitis

Method of measurement

Visual Analogue Scale

3

Description

Burning of the vulva and vagina

Timepoint

before the start of the intervention and 7 days after the end of the intervention

Method of measurement

Visual Analogue Scale

4

Description

White cheesy discharge

Timepoint

before the start of the intervention and 7 days after the end of the intervention

Method of measurement

According to the score obtained from the Sobel scoring system

5

Description

Edema vulva

Timepoint

before the start of the intervention and 7 days after the end of the intervention

Method of measurement

According to the score obtained from the Sobel scoring system

6

Description

Itching of the vulva and vagina

Timepoint

before the start of the intervention and 7 days after the end of the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Improvement of candidal vaginitis

Timepoint

7 days after the end of the intervention

Method of measurement

Removal of symptoms and signs at the beginning and total Sobel severity score ≤ 2 and negative culture

Intervention groups

1

Description

Intervention group: Intervention group: Jashir vaginal cream for one week, one 5 mg applicator every night at bedtime vaginally

Category

Treatment - Drugs

2

Description

Control group: Clotrimazole vaginal cream for one week, one 5 mg applicator every night at bedtime vaginally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's clinic of Yasouj city

Full name of responsible person

Leila Ghayashi

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15 Golestan Street , Yasouj , Kohgiluyeh and Boyer Ahmad Province

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Sponsors / Funding sources

1

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Name of organization / entity

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Full name of responsible person

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Grant name
Yasouj Faculty of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Fatemeh Hekmatzadeh
Position
University professor
Latest degree
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document
Individual data of participants by de-identifying individuals, research results

When the data will become available and for how long
Access period from 1402 to one year

To whom data/document is available
All researchers in academic and scientific institutions

Under which criteria data/document could be used

Study method and statistical analysis

From where data/document is obtainable
To the email address sf.hekmatzadeh@yahoo.com Yasuj University of Medical Sciences, Fatemeh Hekmatzadeh

What processes are involved for a request to access data/document
Request by email or attendance at Yasouj University of Medical Sciences

Comments