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 rand 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 vulvaginitis 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)

Phone

+98 74 3323 5145

Email address

leile.ghiasi.89400000@gmail.com

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-Boyrahmad

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
Street address
15 Golestan Street , Yasouj , Kohgiluyeh and Boyer Ahmad Province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Fatemeh Hekmatzadeh
Street address
No 402, Beach Park towards Imam Sajjad Hospital, Yasouj, Kohgiluyeh and Boyerahmad province
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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
Yasouj University of Medical Sciences
Full name of responsible person
Fatemeh Hekmatzadeh
Position
University professor
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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