Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating and comparing the effects of jujube vaginal cream and Clotrimazole cream on vaginal Candidiasis in women of reproductive age

Protocol summary

Study aim

Determining and comparing the effects of jujube vaginal cream and clotrimazole vaginal cream on vaginal candidiasis in women of reproductive age

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial of 74 eligible women with purposive vaginal candidiasis.

Settings and conduct

The research units will be eligible women with vaginal candidiasis who refer to health care center No. 2 in Mashhad. At the beginning of the study and after 7 days of using the vaginal cream, a vaginal secretion culture test will be performed.

Participants/Inclusion and exclusion criteria

Written consent to participate in the study; have minimum literacy, resident of Mashhad; married and age range 15-49; absence, no use of special medicine in the last two weeks; no allergy to clotrimazole and jujube; no pregnancy or breastfeeding; no use of IUD and hormonal contraceptive method; no recurrent vulvovaginitis candidiasis; no use of oral and topical antifungal (vaginal candidiasis treatment); at least a score of 3 from the total score of symptoms of vaginal candidiasis Bell (according to the questionnaire) and a positive test answer from the candidate's point of view. Conditions of non-entry: occurrence of pregnancy; forgetting the medicine more than once; allergy to the given medicine; use of other antifungals; monthly habit during the study period; intimacy without using a condom and withdrawal of participation in the research by the research unit.

Intervention groups

The intervention group is treated with 3% jujube vaginal cream and 1% clotrimazole every night for one week, and the control group is treated with 1% clotrimazole vaginal cream every night for one week.

Main outcome variables

Treatment success Percent

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221002056076N1**
Registration date: **2023-08-01, 1402/05/10**
Registration timing: **prospective**

Last update: **2023-08-01, 1402/05/10**
Update count: **0**

Registration date

2023-08-01, 1402/05/10

Registrant information

Name

Shima Bahadori

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating and comparing the effects of jujube vaginal cream and Clotrimazole cream on vaginal Candidiasis in women of reproductive age

Public title
Investigating and comparing the effects of jujube vaginal cream and clotrimazole cream on vaginal candidiasis infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Written consent to participate in the study Have minimum literacy Resident of Mashhad Married and age range 15-49 Absence, no use of special medicine in the last two weeks No allergy to clotrimazole and jujube No pregnancy or breastfeeding No use of IUD and hormonal contraceptive method No recurrent vulvovaginitis candidiasis No use of oral and topical antifungal (vaginal candidiasis treatment) At least a score of 3 from the total score of symptoms of vaginal candidiasis Bell (according to the questionnaire) Positive test answer from the candidate's point of view
Exclusion criteria:
Occurrence of pregnancy Forgetting medication more than once Allergy to given medication Use of other antifungals Monthly habit during the study period Intimacy without using condom Withdrawal from participation in the research by the research unit
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is done by the goal-based method and random allocation will be done through blocks of four using the random number table of www.randomization.com site in two groups (intervention and control). The method of concealment will be the allocation of closed envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to blind the jujube vaginal cream and Clotrimazole 1% cream in terms of size, color and smell, they are completely similar and the same tubes are provided to the researcher. Hertiop has a code that the pharmacist consultant is aware of. People who are eligible to enter the study are placed in groups according to the codes and using the table of random numbers. Therefore, until the end of the study, the participant and the researcher will not know about the codes related to Anab vaginal cream and Clotrimazole 1% cream.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
University Street, Doctor's Crossroad, Ibn Sina Street, Faculty of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2023-07-11, 1402/04/20
Ethics committee reference number
IR.MUMS.NURSE.REC.1402.054

Health conditions studied

1

Description of health condition studied
Vaginal candidiasis
ICD-10 code
B37.3
ICD-10 code description
Candidiasis of vulva and vagina

Primary outcomes

1

Description
Vaginal candidiasis
Timepoint
One week ± 24 hours
Method of measurement
Culture of vaginal secretions in the laboratory

Secondary outcomes

1

Description
Itching
Timepoint

Before treatment, one week ± 24 hours after treatment

Method of measurement

Patient history

2

Description

Erythema

Timepoint

Before treatment, one week ± 24 hours after treatment

Method of measurement

Patient history

3

Description

Burning

Timepoint

Before treatment, one week ± 24 hours after treatment

Method of measurement

Patient history

4

Description

Dys paranoia

Timepoint

Before treatment, one week ± 24 hours after treatment

Method of measurement

Patient history

5

Description

The result of the culture of vaginal secretions

Timepoint

Before treatment, one week ± 24 hours after treatment

Method of measurement

Patient history

Intervention groups

1

Description

For one week, treated with 3% jujube vaginal cream and 1% clotrimazole, one applicator every night

Category

Treatment - Drugs

2

Description

Control group: treated with clotrimazole 1% vaginal cream, one applicator every night for one week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center number two

Full name of responsible person

Ali Asghar Mahmoudi

Street address

next to Vahdat Park, Vahdat Boulevard, Panjarah Down Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayor Mobarhan

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Shima Bahadri

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

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Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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