

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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)

##### Phone

+98 937 677 9412

##### Email address

bahadoris982@mums.ac.ir

##### 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  $\pm$  24 hours

#### Method of measurement

Culture of vaginal secretions in the laboratory

## Secondary outcomes

### 1

#### Description

Itching

#### Timepoint

Before treatment, one week  $\pm$  24 hours after treatment

**Method of measurement**

Patient history

**2**

**Description**

Erythema

**Timepoint**

Before treatment, one week  $\pm$  24 hours after treatment

**Method of measurement**

Patient history

**3**

**Description**

Burning

**Timepoint**

Before treatment, one week  $\pm$  24 hours after treatment

**Method of measurement**

Patient history

**4**

**Description**

Dys paranoia

**Timepoint**

Before treatment, one week  $\pm$  24 hours after treatment

**Method of measurement**

Patient history

**5**

**Description**

The result of the culture of vaginal secretions

**Timepoint**

Before treatment, one week  $\pm$  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

**City**

Mashhad

**Province**

Razavi Khorasan

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9153913153

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+98 51 3368 3000

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M2HCenter@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Ghayor Mobarhan

**Street address**

University Research and Technology Vice-Chancellor,  
Mashhad University of Medical Sciences, Daneshgah  
Street

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GhayourM@mums.ac.i

**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

**Street address**

School of Nursing and Midwifery, Ibn Sina Street,  
Doctor's Crossroad, University Street

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Erfanian

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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**Email**

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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