

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Therapeutic Effect of Mixture Honey and Cinnamon Vaginal Cream with Clotrimazole Vaginal Cream for Refine of Sign and Symptom of Vaginal Candidiasis in Women.

Protocol summary

Study aim

Evaluation of the therapeutic effect of mixture of honey and cinnamon vaginal cream with Clotrimazole vaginal cream for refine of sign and symptom in women with vaginal candidiasis

Design

The study is conducted as a randomized triple-blind study with Computer software. The sample size for comparison of two groups determine 100 women are infected with Candidal vulvovaginitis

Settings and conduct

The study is conducted in one of health centers in the city of Hamedan, Hamedan University of Medical Sciences. Clotrimazole vaginal cream and mixture of cinnamon and honey vaginal cream are packaged similarly, and is marked "B" and "A". Samples, researcher, and statistical analysis are unaware of the content of cream. Therefore, the present study is conducted as a Triple-blind study

Participants/Inclusion and exclusion criteria

Exclusion criteria include :being at age of 15 to 45 years old, Signs and symptoms of vaginal candidiasis in interviews, observation and being confirmed by laboratory studies, not being pregnant, no previous use of antifungal drugs, lack of use of broad-spectrum antibiotics during the last two weeks, the lack of allergy to honey and cinnamon being non- diabetic, Exclusion criteria include: pregnancy, lactation, menstruation and abnormal uterine bleeding during treatment.

Intervention groups

In this randomized, triple blind clinical trial of 100 women infected with Candidal vulvovaginitis is placed in two groups of Vaginal cream mixed of cinnamon and honey (N =50) and clotrimazole vaginal cream (N = 50). Both groups is treated for 7 days. At the beginning of study, Clinical and laboratory signs and symptoms are registered 4 and 8 days after treatment by

questionnaire, observation secretions medium culture results.

Main outcome variables

Refine of sign and symptom vaginal candidiasis : Itching, Irritation, Dysuria, Dyspareunia, Discharge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180528039889N1**

Registration date: **2018-06-18, 1397/03/28**

Registration timing: **prospective**

Last update: **2018-06-18, 1397/03/28**

Update count: **0**

Registration date

2018-06-18, 1397/03/28

Registrant information

Name

Tayebeh Rasooli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3252 6270

Email address

rasooli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-20, 1397/03/30

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Therapeutic Effect of Mixture Honey and Cinnamon Vaginal Cream with Clotrimazole Vaginal Cream for Refine of Sign and Symptom of Vaginal Candidiasis in Women.

Public title

Study of the Effect of Mixture Honey and Cinnamon Vaginal Cream in the treatment of Vaginal Candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 15 _45 years Married Not Being Pregnant Not Having Lactation Not Taking Antibiotic Drugs During the 2 Last Weeks Not Taking vaginal Cream During 2 Last Weeks Not Having Medical Disease Not Having Allergy to Honey or Cinnamon Not Taking Oral Contraceptive Confirming Candida Infection Not Having Recurrent Candida Infection

Exclusion criteria:

To Have Tricomona or Gardenella Vaginitis Not Agreeing to Participate in the Study Not Using Drug Having Vaginal Bleeding

AgeFrom **15 years** old to **45 years** old**Gender**

Female

Phase

0

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization with Computer software

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient is asked to fill out the letter of consent to participate in the study and randomly is assigned to two groups, case and control. Clotrimazole Vaginal cream and Honey and cinnamon Vaginal cream are packaged similarly and is marked "A" and "B" by a pharmacist. Creams are applied each night as an applicator (5 g) inside the vagina for 7 nights. Samples, research group, and statistical analysis are unaware of the content of cream. Therefore, the present study is conducted as a Triple-blind study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

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Shahid Beheshti Univercity of Medical Science

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-10-09, 1396/07/17

Ethics committee reference number

IR.SBMU.PHNM.1396.850

Health conditions studied**1****Description of health condition studied**

Candidal Vaginitis

ICD-10 code

N77.1

ICD-10 code description

Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere

Primary outcomes**1****Description**

Itching

Timepoint

Before treatment, 4 and 8 day after treatment

Method of measurement

check list

2**Description**

Irritation

Timepoint

Before treatment, 4 and 8 day after treatment

Method of measurement

check list

3

Description

Dyspareunia

Timepoint

Before treatment, 4 and 8 day after treatment

Method of measurement

check list

4

Description

Dysuria

Timepoint

Before treatment, 4 and 8 day after treatment

Method of measurement

check list

5

Description

Discharge

Timepoint

Before treatment, 4 and 8 day after treatment

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: mixture honey and cinnamon vaginal cream each night as an applicator (5 gram) inside the vagina for 7 nights including honey 30% and cinnamon 2%.

Category

Treatment - Drugs

2

Description

Control group: Clotrimazole vaginal cream each night as an applicator (5 gram) inside the vagina for 7 nights.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Health center

Full name of responsible person

Tayebeh Rasooli

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Buali street

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tayebeh Rasooli

Position

Master of science student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Ph.D.

Other areas of specialty/work

Health Promotion

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable