

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparison of the effect of honey vaginal cream and combination of honey and yoghurt vaginal cream for the treatment of vulvovaginal candidiasis

#### Protocol summary

##### Summary

This study is a triple blind clinical trial and randomized has conducted with the purpose of determination and comparison of the effect of honey vaginal cream and combination of honey and yoghurt vaginal cream for the treatment of vulvovaginal candidiasis in women whom referred to sari health medical center. In this clinical trial, 105 women with known candidiasis will be randomly allocated into three groups. Each group will be 35 person. Drugs consist of: combination of honey and yoghurt, honey and clotrimazole vaginal creams. To hide the allocation, the creams will be prepared in Armaghan teb pharmacy laboratory medicine of tehran and they will be put in quit similar packages and will be available to researcher with codes A,B,C. Data collection was accomplished demographic information questionnaire and clinical performance checklist. Patients will be randomly allocated in groups A,B,C and each group will receive a vaginal cream with the same code similar to the group. The creams are using intra vaginal one applicator every night for 7 nights. They will be recommended to comply with health issues and do not use douching, other vaginal drugs and also herbal and systemic drugs during study period. We will ask participants to come back 7 days and 14 days after initiation of treatment for evaluation of treatment and relapse, respectively. The infection diagnosis and evaluation of treatment and relapse will be based on clinical symptoms, assessment of vaginal pH, direct observation and culture.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201401052248N14**  
Registration date: **2014-06-24, 1393/04/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-06-24, 1393/04/03

##### Registrant information

###### Name

Fereshteh Jahdi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

00982188773073,00982182471404

###### Email address

f.jahdi@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mazandaran University of Medical Sciences"

##### Expected recruitment start date

2014-03-21, 1393/01/01

##### Expected recruitment end date

2014-06-15, 1393/03/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of honey vaginal cream and combination of honey and yoghurt vaginal cream for the treatment of vulvovaginal candidiasis

**Public title**

Effect of yogurt and honey in the treatment of vulvovaginal candidiasis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Women were married and aged between 18-45 years old; Not being pregnancy, lactation and menopausal period; Not having any vaginal bleeding; No history of allergy to honey ;Not using antifungal drugs for 2 weeks before the study; Not using vaginal cream for last 48 hours before the study; Not using antibiotic and corticosteroids in the past two weeks; Patient with vaginal candidiasis. Exclusion criteria: Existance of other vaginal infections; Pregnancy in the study time table; Having any known choronic disease; Participation at another trial; Drugs intolerance.

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **105**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethical commitment of Tehran University of Medical Sciences

**Street address**

Sixth floor ,Central office, Ghods St, Keshavarz Blvd

**City**

tehran

**Postal code****Approval date**

2014-03-12, 1392/12/21

**Ethics committee reference number**

130/3005/92/3

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

Vulvovaginal Candidiasis

**ICD-10 code**

N37.3

**ICD-10 code description**

Candidiasis of Vulva and Vagina

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

Improve Vulvovaginal Candidiasis

**Timepoint**

7 Days After Treatment

**Method of measurement**

Questionnaire, Microscopic evaluation, Secretion culture, Measurements Of Ph

**Secondary outcomes****1****Description**

Improve Of Vulvovaginal Candidiasis

**Timepoint**

14 Day After Treatment

**Method of measurement**

Questionnaire, Microscopic evaluation, Measurements Of Ph

**Intervention groups****1****Description**

The intervention group:vaginal cream of yogurt& honey:One applicator Once a Day

**Category**

Treatment - Drugs

**2****Description**

The intervention group:vaginal cream of honey:One applicator Once a Day

**Category**

Treatment - Drugs

**3****Description**

Control: Clotrimazole Vaginal Cream :One applicator Once a Day

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Sari Hospital Gynecology Clinic

**Full name of responsible person**

Mari Darvishi, Graduate student Midwifery

**Street address**

Sari, Amir Mazandarani ST

**City**

Sari

### 2

#### Recruitment center

**Name of recruitment center**

Health center 17

**Full name of responsible person**

Mis Maria Mahmodi

**Street address**

Sari, Keshavarz Bulvar

**City**

Sari

### 3

#### Recruitment center

**Name of recruitment center**

Health center 5

**Full name of responsible person**

Mis Vhide Entezari

**Street address**

Sari, Salman Farsi, Alley way Gofran

**City**

Sari

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Sciences vice chancellor for research- Tehran University of Medical Sciences

**Street address**

Keshavarz Blvd, Qods St., Central University, Sixth Floor

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mari Darvishi

**Position**

Midwifery student

**Other areas of specialty/work****Street address**

Sari, Peyvandi, Peyvand 9

**City**

Sari

**Postal code****Phone**

+98 15 1322 6196

**Fax****Email**

sepide\_d77@yahoo.com

**Web page address**

www.fnm.tums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences, School of Midwifery and Nursing

**Full name of responsible person**

Fereshteh Jahdi

**Position**

Master of midwifery

**Other areas of specialty/work****Street address**

Midwifery dep, School of Nursing Midwifery, Tehran University of Medical Sciences, West Nosrat St, Tohid Sq, Tehran, Iran

**City**

Tehran

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences, School of  
Midwifery and Nursing

**Full name of responsible person**

Fereshteh Jahdi

**Position**

Master of midwifery

**Other areas of specialty/work****Street address**

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Sq, Tehran, Iran

**City**

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**Fax****Email**

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**Web page address**

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*