

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparison of the effect of compound vaginal cream (honey, olive oil and propolis) versus Clotrimazole vaginal cream on candida vaginitis in fertile women: a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

Comparison of the effect of compound vaginal cream (honey, olive oil and propolis) versus Clotrimazole vaginal cream on candida vaginitis among fertile women

##### Design

This is a double-blind randomized clinical trial, phase II, in which 116 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible fertile women who will refer to Health Centers in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 44 years Married fertile women Candida vaginitis Exclusion criteria: Current using antifungal, antibiotic, immunosuppressive drugs or OCP Unusual uterine bleeding Recurrent Vulvo vaginitis Pregnancy Breastfeeding Using alcohol

##### Intervention groups

Intervention group Compound vaginal cream (honey, olive oil and propolis) 60 g every night using the intravaginal applicator for 7 days Control group: Clotrimazole vaginal cream 1% 5 g every night using the intravaginal applicator for 7 days

##### Main outcome variables

Primary outcome: Assessing the vaginal lesions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N290**

Registration date: **2019-08-16, 1398/05/25**

Registration timing: **prospective**

Last update: **2019-08-16, 1398/05/25**

Update count: **0**

##### Registration date

2019-08-16, 1398/05/25

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-23, 1398/06/01

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of compound vaginal cream (honey, olive oil and propolis) versus Clotrimazole

vaginal cream on candida vaginitis in fertile women: a double-blind randomized clinical trial

#### Public title

Comparison of the effect of compound vaginal cream (honey, olive oil and propolis) versus Clotrimazole vaginal cream on candida vaginitis in fertile women

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age of 18 to 44 years Married fertile women Candida vaginitis

##### Exclusion criteria:

Current using antifungal, antibiotic, immunosuppressive drugs or OCP Unusual uterine bleeding Recurrent Vulvo vaginitis Pregnancy Breastfeeding Using alcohol

#### Age

From **18 years** old to **44 years** old

#### Gender

Female

#### Phase

2

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

#### Sample size

Target sample size: **116**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

#### Approval date

2019-06-19, 1398/03/29

#### Ethics committee reference number

IR.UMSHA.REC.1398.347

## Health conditions studied

### 1

#### Description of health condition studied

Candida vaginitis

#### ICD-10 code

N76.0

#### ICD-10 code description

Acute vaginitis

## Primary outcomes

### 1

#### Description

Assessing the vaginal lesions

#### Timepoint

Before the intervention and one week after the intervention

#### Method of measurement

By physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group Compound vaginal cream (honey, olive oil and propolis) 60 g every night using intravaginal applicator for 7 days

#### Category

Treatment - Drugs

## 2

### Description

Control group: Clotrimazole vaginal cream 1% 5 g every night using intravaginal applicator for 7 days

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health Centers in Hamadan City

##### Full name of responsible person

Arezoo Shayan

##### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

##### City

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+98 81 3838 0572

##### Email

Arezoo.shayan2012@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Arezoo Shayan

##### Position

Master of Midwifery

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Seyedeh Zahra Masoumi

##### Position

Reproductive Health Specialist

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Reproductive Health

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**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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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