

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Effect of vaginal suppositories containing essential oil of Zataria Multiflora versus Leucorex cream on clinical symptoms in patients with candida vaginitis: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of vaginal suppositories containing essential oil of Zataria Multiflora versus Leucorex cream on clinical symptoms in patients with candida vaginitis

##### Design

This is a randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

##### Settings and conduct

This study will be performed in the Comprehensive Health Centers on 80 eligible patients. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. Blinding is not possible in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 44 years; Candida vaginitis; Exclusion criteria: Pregnancy or breastfeeding; Taking any antiparasitic drugs, antibiotics, or immunosuppressive drugs in the past two weeks; Abnormal uterine bleeding; Alcohol consumption; Chronic diseases including liver failure, diseases of the central nervous system, dyskriasias, diabetes, immune deficiency

##### Intervention groups

Intervention group: Using vaginal suppositories containing essential oil of Zataria Multiflora every night for one week Control group: Using Leucorex cream 50 mg every night for one week

##### Main outcome variables

Primary outcome: Signs and symptoms of candida vaginitis

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20120215009014N420**

Registration date: **2022-03-16, 1400/12/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-03-16, 1400/12/25**

Update count: **0**

#### Registration date

2022-03-16, 1400/12/25

#### 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

2022-03-16, 1400/12/25

#### Expected recruitment end date

2022-05-21, 1401/02/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of vaginal suppositories containing essential oil of Zataria Multiflora versus Leucorex cream on clinical symptoms in patients with candida vaginitis: a randomized clinical trial

**Public title**

Effect of vaginal suppositories containing essential oil of Zataria Multiflora versus Leucorex cream on clinical symptoms in patients with candida vaginitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 18 to 44 years; Candida vaginitis;

**Exclusion criteria:**

Pregnancy or breastfeeding; Taking any antiparasitic drugs, antibiotics, or immunosuppressive drugs in the past two weeks; Abnormal uterine bleeding; Alcohol consumption; Chronic diseases including liver failure, diseases of the central nervous system, dyskriasias, diabetes, immune deficiency

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****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**

2020-05-05, 1399/02/16

**Ethics committee reference number**

IR.UMSHA.REC.1399.078

**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**

Signs and symptoms of candida vaginitis

**Timepoint**

Before the intervention and one week after that

**Method of measurement**

Through taking history and clinical examination

**Secondary outcomes**

empty

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

Intervention group: Using vaginal suppositories containing essential oil of Zataria Multiflora every night for one week

**Category**

Treatment - Drugs

**2****Description**

Control group: Using Leucorex cream 50 mg every night for one week

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Comprehensive Health Centers in Hamadan city

**Full name of responsible person**

Neda Safari

**Street address**

School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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6517838695

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+98 81 3838 0572

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neda.safari.7596@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokoohi

**Street address**

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**

Neda Safari

**Position**

Student of Pharmacy

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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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. Farzin Firozan

**Position**

Pharmacologist

**Latest degree**

Medical doctor

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Medical Pharmacy

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ffirozian@yahoo.com

## 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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**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