

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

Phone

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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

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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

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

Other areas of specialty/work

Medical Pharmacy

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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