Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of combined vaginal cream (including honey, olive oil, and propolis) versus placebo with antibiotic therapy on improvement of cervicitis symptoms: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of combined vaginal cream (including honey, olive oil, and propolis) versus placebo with antibiotic therapy on improvement of cervicitis symptoms.

Design

This is a double-blind randomized clinical trial, phase III, in which 66 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with cervicitis referring to the 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 examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 44 years, Cervicitis, Married, Exclusion criteria: Pregnancy or breastfeeding, Taking antibiotic or immunosuppressive medications to vaginal drugs in the past 2 weeks, Abnormal uterine bleedings, Abnormal Pop-smear test in the past 12 months, Repeated vaginal shower, Alcohol consumption, Liver, renal, hematologic, or central nerves system diseases or diabetes or immunodeficiency syndrome

Intervention groups

Intervention group: Tablet azithromycin 1 g single-dose and tab cefixime 400 mg single-dose and tablet metronidazole 500 mg daily for 7 days patient and her husband plus combined vaginal cream (containing honey, olive, propolis) every night for 14 nights Control group: Tablet azithromycin 1 g single-dose and tab cefixime 400 mg single-dose and tablet metronidazole 500 mg daily for 7 days patient and her husband plus placebo vaginal cream (containing oil) every night for 14 nights

Main outcome variables

Primary outcome: Symptoms of cervicitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N383**
Registration date: **2021-02-08, 1399/11/20**
Registration timing: **prospective**

Last update: **2021-02-08, 1399/11/20**
Update count: **0**

Registration date

2021-02-08, 1399/11/20

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of combined vaginal cream (including honey, olive oil, and propolis) versus placebo with antibiotic therapy on improvement of cervicitis symptoms: a double-blind randomized clinical trial

Public title

Effect of combined vaginal cream (including honey, olive oil, and propolis) versus placebo with antibiotic therapy on improvement of cervicitis symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 44 years, Cervicitis, Married,

Exclusion criteria:

Pregnancy or breastfeeding, Taking antibiotic or immunosuppressive medications to vaginal drugs in the past 2 weeks, Abnormal uterine bleedings, Abnormal Pop-smear test in the past 12 months, Repeated vaginal shower, Alcohol consumption, Liver, renal, hematologic, or central nerves system diseases or diabetes or immunodeficiency syndrome

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **66**

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

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

2021-01-30, 1399/11/11

Ethics committee reference number

IR.UMSHA.REC.1399.902

Health conditions studied

1

Description of health condition studied

Cervicitis

ICD-10 code

A54.03

ICD-10 code description

Gonococcal cervicitis, unspecified

Primary outcomes

1

Description

Symptoms of cervicitis

Timepoint

Before the intervention and 14 days later

Method of measurement

By taking history and vaginal examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Tablet azithromycin 1 g single-dose and tab cefixime 400 mg single-dose and tablet metronidazole 500 mg daily for 7 days patient and her husband plus combined vaginal cream (containing honey, olive, propolis) every night for 14 nights
Category
Treatment - Drugs

2

Description
Tablet azithromycin 1 g single-dose and tab cefixime 400 mg single-dose and tablet metronidazole 500 mg daily for 7 days patient and her husband plus placebo vaginal cream (containing oil) every night for 14 nights
Category
Placebo

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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Master of Midwifery
Latest degree
Master
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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