Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 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 Volvo 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

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Iran (Islamic Republic of)

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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 Volvo 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
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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
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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
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Person responsible for updating data

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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