Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effect of Hypericum perforutum Vaginal gel and Clotrimazole Vaginal cream on Vaginal Candida albicans infection: A double-blind randomized clinical trial

Protocol summary

Study aim

Determining and comparing the effects of Hypericum perforutum vaginal gel and clotrimazole vaginal cream on vaginal Candida albicans infection

Design

This is a randomized, double-blind, controlled clinical trial. which has a parallel group and will be performed on 80 patients with inclusion criteria. Random block method is used for randomization.

Settings and conduct

The research environment will be Shahid Mofateh Clinic in Yasuj city.The service provider screens the patients along with the gynecologist. For the final confirmation of the diagnosis, a serological test will be taken from the vaginal secretions. Only the pharmacist knows the type of drug used, and the researcher and service provider, the out come assessor and analyst, and the patient will be unaware of the type of drug used.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Women of reproductive age (18-49) 2- Presence of cheesy vaginal discharge and doctor's confirmation 3- Complaints of burning, itching and swelling and pain in the vulva and vagina Exclusion criteria: 1- Lactating women 2- Pregnant women 3- Women who smoke 4- The possibility of starting menstruation in the next 10 days 5- Having intercourse in the last 24 hours 6- Washing the vagina and using vaginal medicine in the last 48 hours 8- History of candida vaginitis

Intervention groups

The intervention group includes women who presented with complaints of candida vaginitis symptoms and after the final diagnosis through clinical symptoms and serological tests, Hypericum perforutum vaginal cream therapeutic intervention will be performed on them.

Main outcome variables

Itching، Burning، the pain، Inflammation، Cheesy secretions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231017059753N1**
Registration date: **2023-12-20, 1402/09/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-20, 1402/09/29**
Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

leila bozorgian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of Hypericum perforutum Vaginal gel and Clotrimazole Vaginal cream on Vaginal Candida albicans infection: A double-blind randomized clinical trial

Public title
Comparison of the effect of Hypericum perforutum Vaginal gel and Clotrimazole Vaginal cream on Vaginal Candida albicans infection: A double-blind randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1- Women of reproductive age (18-49)- 2- Presence of cheesy vaginal discharge and doctor's confirmation 3- Complaints of burning, itching and swelling and pain in the vulva and vagina 4- Absence of other vaginal infections 5- Willingness to participate in the study 6- Women with sexual partners

Exclusion criteria:
1- Lactating women 2- Pregnant women 3- Women who smoke 4- The possibility of starting menstruation in the next 10 days 5- Having abnormal vaginal bleeding at the time of sampling 6- Having intercourse in the last 24 hours 7- Washing the vagina and using vaginal medicine in the last 48 hours 8- Having a history of any type of transplantation and using immunosuppressive drugs and broad-spectrum antibiotics, hormonal drugs and combined contraceptive pills, anti prostaglandins and anticoagulant drugs in the last month, and antiepileptic and migraine drugs or women with Heart and kidney diseases or sexually transmitted diseases. 9- History of Candida infection in the last 6 months and its treatment 10- History of candidal vaginitis

Age
From **18 years** old to **49 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be in the form of random block sampling based on the purpose and according to the study entry criteria. We consider the block size to be 5. Therefore, based on the sample size, we will have 20 blocks. When sampling starts, the first block will be randomly assigned one of the codes A or B. Based on the received code of the first block, the second code will be sent to the second block, the first code will be sent to the third block, the second code will be sent to the fourth block, and so on until the end of the 20th block.

Blinding (investigator's opinion)
Double blinded

Blinding description
Hypericum perforutum vaginal gel and Clotrimazole vaginal cream have already been compared by the pharmacist in terms of appearance, color, size, smell and coded (A and B). The researcher, the service provider, the data analyst and the patient are unaware of the type of drug used, and only the pharmacist will be aware of this coding.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Yasuj University of Medical Sciences

Street address
Shahid Motahari St., Yasouj University of Medical Sciences, Research Assistant

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Approval date
2023-10-31, 1402/08/09

Ethics committee reference number
IR.YUMS.REC.1402.132

Health conditions studied

1

Description of health condition studied
Candida vaginitis

ICD-10 code
N76.1

ICD-10 code description
Subacute and chronic vaginitis

Primary outcomes

1

Description
Itching
Timepoint
Results will be measured ten days to two weeks after the end of the treatment period.
Method of measurement
The way to measure the variable will be through a laboratory test and also a researcher-made questionnaire of clinical symptoms

2

Description
Burning
Timepoint
Results will be measured ten days to two weeks after the end of the treatment period.
Method of measurement
The way to measure the variable will be through a laboratory test and also a researcher-made questionnaire of clinical symptoms

3

Description
vaginal pain
Timepoint
Results will be measured ten days to two weeks after the end of the treatment period.
Method of measurement
The way to measure the variable will be through a laboratory test and also a researcher-made questionnaire of clinical symptoms.

4

Description
Inflammation
Timepoint
Results will be measured ten days to two weeks after the end of the treatment period.
Method of measurement
The way to measure the variable will be through a laboratory test and also a researcher-made questionnaire of clinical symptoms.

5

Description
Cheesy secretions
Timepoint
Results will be measured ten days to two weeks after the end of the treatment period.
Method of measurement
The way to measure the variable will be through a laboratory test and also a researcher-made questionnaire of clinical symptoms.

Secondary outcomes

1

Description
Satisfaction with treatment
Timepoint
One week to ten days after the intervention
Method of measurement
questionnaire

Intervention groups

1

Description
The intervention group will use the vaginal gel of gerbera prepared by the pharmacist with a concentration of 3%. After manufacturing, it is poured into sterilized tubes and placed in a box with 5 applicators. Each applicator contains 5 grams of cream, which the patient is instructed to use every night for 5 nights. Explanations regarding not using other drugs and antibiotics and not using vaginal douche and other vaginal drugs during the treatment period will be given to the intervention group.
Category
Treatment - Drugs

2

Description
Control group: The control group will be clotrimazole vaginal cream. Tubes of Clotrimazole Vaginal Cream and Calendula Gel will match in terms of color, smell, size and shape. Each applicator contains 5 grams of cream, which the patient is instructed to use every night for 5 nights. Explanations regarding not using other drugs and antibiotics and not using vaginal douche and other vaginal drugs during the treatment period will be given to the control group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
15 Golestan St, Shahid Moftah Clinic، Yasuj
Full name of responsible person
Leila Bozorgian
Street address
Shahid Jalil St., Educational Campus, Medicinal Plants Research Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
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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
Yasouj 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

2

Sponsor
Name of organization / entity
Vice President of Research and Technology of Yasouj University of Medical Sciences
Full name of responsible person
Dr. Sayed Amin Hosseini motlagh
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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
Vice President of Research and Technology of Yasouj 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
Yasouj University of Medical Sciences
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Leila Bozorgian
Position
Midwifery Instructor
Latest degree
Master
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Midwifery
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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