Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

the therapeutic effects of vaginal cream of bunium persicum (black zera) on candida albicans vaginitis

Protocol summary

Study aim
Determining effects of vaginal cream of bunium persicum (black zera) on candida albicans vaginitis

Design
Triple blinded clinical trial, parallel groups, Phase 2 on 100 women Random allocation with software Minitab11

Settings and conduct
The researcher goes to the clinic of Kashani Hospital in Jiroft and, by explaining the objectives, receives written written consent. Sampling is performed by two sterile cotton swabs from the lateral wall and vaginal discharge. On the second slide, add a 10% potash drop, and if the mycelium or hyphae blastopur was under a microscope, the sample is positive. The second swab for smear and staining with Gimsa to more accurately diagnose mycelium is Hif Yablastopur, and if the second lam is positive, 10 landa removes vaginal discharge and is cultured for 48 hours on a chrom agar medium at 27 C sel. In the first stage, the samples will be randomly divided into two groups: clotrimazole ointment and black cumin. They use clotrimazole ointment or Kermani black cumin for 7 nights. The instructions for use are called cream and hygienic recommendations. Drugs are followed up, they are taken out of the study with drug side effects. On day 8, the sample will be taken again and culture will be performed

Participants/Inclusion and exclusion criteria
Married women 49-15 years of age,no pregnancy or lactation,no antifungal use,no antibiotics in recent weeks,no hypersensitivity to black bean colostrum,no chronic disease Output criteria: overuse of forgetfulness, drug allergy or intolerance,pregnancy,vaginal bleeding, and unwillingness to cooperate

Intervention groups
Black cumin and clotrimazole ointment

Main outcome variables
Improving and accelerating the treatment of candid vaginitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200415047087N1**
Registration date: **2020-06-09, 1399/03/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-09, 1399/03/20**
Update count: **0**

Registration date
2020-06-09, 1399/03/20

Registrant information

Name
sareh mehni

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 4331 5306

Email address
sa.mehni@jmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2021-01-20, 1399/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

the therapeutic effects of vaginal cream of bunium persicum (black zera) on candida albicans vaginitis

Public title

the therapeutic effects of vaginal cream of bunium persicum (black zera) on candida albicans vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women in the age range of 15-49 years No pregnancy or breastfeeding Do not use oral or topical antifungals to treat vaginal infections in the last two weeks Lack of sensitivity to clotrimazole and black cumin Lack of use of antibiotics and immunosuppressive drugs in the last two weeks Not suffering from chronic diseases such as diabetes

Exclusion criteria:

More than once forgetting to use medication Sensitivity or intolerance to the drug used get pregnant Abnormal vaginal bleeding Lack of willingness to cooperate with participants

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be such that in the mini-tab software of version 11, the numbers 1-100 are entered, then 50 pieces will be selected randomly by this software. People who have entered the study number with the same 50 selected numbers will be given drug A and the remaining 50 people will be given drug B.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, participants will be blinded by the shape, size and smell of ointments. Also, to blind the researcher and analyze the data, the drugs will be divided into two groups A and B without their knowledge of each group, and thus blinding these people will be done.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jiroft University of Medical Sciences

Street address

Pasdaran Blvd

City

Jiroft

Province

Kerman

Postal code

7861763730

Approval date

2017-01-20, 1395/11/01

Ethics committee reference number

IR.JMU.REC.1395.14

Health conditions studied

1

Description of health condition studied

Vulvo vaginal Candidiasis

ICD-10 code

N77.1

ICD-10 code description

Vaginitis, vulvitis and vulvovaginitis in infectious and parasitic diseases classified elsewhere

Primary outcomes

1

Description

Percentage of women with positive vaginal discharge for candid vaginitis

Timepoint

1 and 8 day

Method of measurement

Chromium agar culture medium

Secondary outcomes

1

Description

Cultivation of vaginal secretions for candid vaginitis

Timepoint

8 day

Method of measurement

Chromium agar culture medium

Intervention groups

1

Description

Intervention group: Women treated with black cumin

ointment, 1% black cumin ointment, one application every night for 7 nights, It has been prepared in the Faculty of Pharmacy of Kerman University of Medical Sciences

Category
Treatment - Drugs

2

Description
Control group: Women treated with clotrimazole ointment, 1% clotrimazole ointment made by Pars Daru Company, one applicator for 7 nights every night

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Kashani Hospital in Jiroft

Full name of responsible person
Sareh Mehni

Street address
Nurse Street

City
Jiroft

Province
Kerman

Postal code
7861733616

Phone
+98 34 4326 2401

Email
sareh.mehni@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jeeroft University of Medical Sciences

Full name of responsible person
Fatemeh Seydi

Street address
Pasdaran Boulevard

City
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Postal code
7861763730

Phone
+98 34 4331 7302

Email
fa.seydi@jmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Jiroft 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
Jeeroft University of Medical Sciences

Full name of responsible person
Sareh Mehni

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Jeeroft University of Medical Sciences

Full name of responsible person
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Position
Instructor

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Person responsible for updating data

Contact
Name of organization / entity
Jeeroft University of Medical Sciences
Full name of responsible person
Sareh Mehni
Position
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Latest degree
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Other areas of specialty/work
Midwifery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
In this study, the study protocol, statistical analysis map and conscious consent form will be published.
When the data will become available and for how long
1400
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Give citation if used
From where data/document is obtainable
sa.mehni@jmu.ac.ir
What processes are involved for a request to access data/document
The applicant must send an e-mail to the e-mail address listed in the previous section. Then their e-mail will be checked and finally, at the first opportunity, their request will be answered within a maximum of one week and the desired document will be sent.
Comments