Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A comparetive study of Arnebia Euchroma Vaginal Cream and Clotrimazole Vaginal Cream’s effectiveness on Candida Vulvovaginitis

Protocol summary

Study aim

Evaluation of the Arnebia Euchroma effectiveness on Candida Vulvovaginitis

Design

This is a clinical trial with 60 patients sample size. Eligible patients will be enrolled after obtaining consent form, randomly assigned, into two groups. Sama Vaginal Cream is manufactured by Mashhad School of Pharmacy Lab. In this study the Patient, the Mycologist and the Analyzer will not know the type of drug that used. For this purpose, two type of drug are placed in similar tubes.

Settings and conduct

Eligible patient will be enrolled into two groups after obtaining consent form. At the beginning and at the end of treatment, vaginal discharge specimens are taken from the patient in the central laboratory of Mashhad Imam Reza Hospital to investigate the presence of a candida in direct slide and culture. The second visit is made two days after the start of treatment to evaluate the side effects of the medication. If cases has complication with herbal medicine, the treatment will switch to standard treatment. On the seventh day after treatment, patients will be examined and a sample of discharge will be taken for laboratory examination. The result is based on clinical observation and laboratory specimen. In this stage, if no response to treatment in intervention group, standard treatment will be considered.

Participants/Inclusion and exclusion criteria

All patients with Candida Vulvovaginitis who are not pregnant, comorbidity such as Diabetes , Hypertention and etc. or medications are included in the study.

Intervention groups

group 1: Prescribing Sama Vaginal Cream one applicator each night for seven days group 2: Prescribing Clotrimazole Vaginal Cream one applicator each night for seven days

Main outcome variables

Age; Presence of infection; Hypersensitivity; Abdominal cramp; Dyspareunia; Dysuria; frequency ; Study groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190303042889N2**
Registration date: **2021-04-04, 1400/01/15**
Registration timing: **retrospective**

Last update: **2021-04-04, 1400/01/15**
Update count: **0**

Registration date

2021-04-04, 1400/01/15

Registrant information

Name

Zahra Habibian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3221 4363

Email address

habibiannezhadz971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

2017-04-21, 1396/02/01

Actual recruitment end date

2019-10-22, 1398/07/30

Trial completion date
2019-10-30, 1398/08/08

Scientific title
A comparetive study of Arnebia Euchroma Vaginal Cream and Clotrimazole Vaginal Cream’s effectiveness on Candida Vulvovaginitis

Public title
A comparetive study of Arnebia Euchroma Vaginal Cream and Clotrimazole Vaginal Cream’s effectiveness on Candida Vulvovaginitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candida Vulvovaginitis
Exclusion criteria:
Pregnancy Comorbidity Medication

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **62**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Cases, Mycologist and Analyzer won't know about type of drugs; Therefore two types of drug have been placed in the same tubes. After completing the research, based on the color of the substance in the tube, the researcher will identify the type of drug in each group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical,Daneshgah Ave.,Mahhad
City
Mashhad
Province
Razavi Khorasan
Postal code
1394491388

Approval date
2013-08-17, 1392/05/26

Ethics committee reference number
IR.MUMS.REC.1392.127

Health conditions studied

1

Description of health condition studied
Candidiasis Vulvuvaginitis

ICD-10 code
B37.3

ICD-10 code description
Candidiasis of vulva and vagina

Primary outcomes

1

Description
Candidiasis Vulvuvaginitis in direct smear of vaginal discharge

Timepoint
Baseline and the end of the treatment

Method of measurement
Presence of Candida in direct smear of vaginal discharge

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Use of vaginal ointment 1% aqueous extract of Onosma dichroanthum Boissmade in Mashhad School of Pharmacy, one applicator a day for 7 days

Category
Treatment - Drugs

2

Description
Intervention group: Use clotrimazole vaginal ointment 1% once a day for 7 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Health Center No. 2

Full name of responsible person
Seyedeh Zahra Habibiannezhad

Street address
Mashhad Health Center No. 2, Vahdat Blvd.

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Ch-mashhad2@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Tafaghodi Mohsen

Street address
Mashhad University of Medical Sciences, Daneshgah street

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Email
vcresearch@mums.ac.ir

Web page address
http://v-research.mums.ac.ir/

Grant name

Grant code / Reference number
4900

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
70

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
Mashhad University of Medical Sciences

Full name of responsible person
Seyedeh Zhahra HabibianNejad

Position
Phamily Medicine student

Latest degree
Medical doctor

Other areas of specialty/work
Family Physician

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Variables related to cases such as age can be shared
When the data will become available and for how long
12 months after the article was published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
It can be accessed when needed for project design
From where data/document is obtainable
By sending a request to the researcher's email
What processes are involved for a request to access data/document
After emailing the request, the information will be emailed after maximum two weeks
Comments