

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### A comparative study of Arnebia Euchroma Vaginal Cream and Clotrimazole Vaginal Cream's effectiveness on Candida Vulvovaginitis

#### Protocol summary

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

#### 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

#### 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 comparative study of Arnebia Euchroma Vaginal Cream and Clotrimazole Vaginal Cream's effectiveness on Candida Vulvovaginitis

**Public title**

A comparative 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 Vulvovaginitis

**ICD-10 code**

B37.3

**ICD-10 code description**

Candidiasis of vulva and vagina

**Primary outcomes****1****Description**

Candidiasis Vulvovaginitis 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 Habibianneshad

**Street address**

Mashhad Health Center No. 2, Vahdat Blvd.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9153913153

**Phone**

+98 51 3365 3000

**Email**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3841 2081

**Fax**

+98 51 3843 0249

**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

**Street address**

No 11, Etemad Ave, Khosravi Ave

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**Email**

Habibianneshadz971@mums.ac.ir

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyedeh Zhahra HabibianNejad

**Position**

Family Medicine Student

**Latest degree**

Medical doctor

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyede Zhahra HabibianNejad

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**Latest degree**

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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**