

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of vaginal cream of grape seed extract and clotrimazole on the treatment of candida vaginitis: a randomized clinical trial

Protocol summary

Study aim

Determining the comparative effect of grape seed extract vaginal cream and clotrimazole on the treatment of candidal vaginitis

Design

A controlled, parallel-group, three-blind, randomized clinical trial on 70 patients with candidal vaginitis.

Settings and conduct

Women with vaginitis referred to women's clinics of hospitals affiliated to Ahvaz University of Medical Sciences. Then the women are examined and the symptoms are observed. Samples are taken from vaginal secretions and transferred to the laboratory, and after confirmation of candida vaginitis, clotrimazole cream or grape extract is given according to the group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent to participate in the research, diagnosis of candidal vaginitis, not suffering from diabetes mellitus and diseases that weaken the immune system, not using broad-spectrum antibiotics in the last 2 weeks, not using vaginal douches in the last 48 hours, not using Vaginal drugs during the last week and also not using hormonal drugs during the last 3 months, not having iodine, not having candida infection more than 4 times a year. Non-entry criteria: vaginal bleeding, grape allergy, pregnancy and breastfeeding

Intervention groups

In both groups (grape extract cream and clotrimazole cream), patients will be asked to use one applicator (5 grams) of the cream intravaginally for one week.

Main outcome variables

Duration of treatment, burning, itching, secretions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181214041963N3**

Registration date: **2023-03-08, 1401/12/17**

Registration timing: **prospective**

Last update: **2023-03-08, 1401/12/17**

Update count: **0**

Registration date

2023-03-08, 1401/12/17

Registrant information

Name

Atefeh Ebrahimiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3420 0651

Email address

ebrahimiyani27@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vaginal cream of grape seed extract and clotrimazole on the treatment of candida

vaginitis: a randomized clinical trial

Public title

The effect of grape seed extract vaginal cream on the treatment of candidal vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in research
Diagnosis of candidal vaginitis (at least 3 points out of 18 symptom points),
Marriage history
Not being pregnant
Lack of breastfeeding
Not suffering from diabetes mellitus and diseases that weaken the immune system
Not using broad-spectrum antibiotics in the last 2 weeks
Not using vaginal douche in the last 48 hours
Not using vaginal drugs during the last week
Not using hormonal drugs during the last 3 months
Not having audio
Not having a candidal infection more than 4 times a year

Exclusion criteria:

Vaginal bleeding
Addiction and alcohol consumption
Allergy to grapes

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by the available method, in such a way that married and non-pregnant women who refer to the women's clinic of Ahvaz University of Medical Sciences due to candidal vaginitis and are eligible to enter the study are selected. The research units will be assigned to two intervention and control groups using the random block method (six blocks). In this way, the 6 possible states of the blocks (AABB, ABAB, BBAA, BABA, ABBA, BAAB) will be listed first. And each block will be assigned a number from one to six. Then a number between one and six is randomly selected using the random number table, and then people are selected based on the block corresponding to the number. will be assigned to the intervention (A) and control (B) groups. This work will continue until the sample volume is completed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Grape extract cream and Clotrimazole cream will be specified by the pharmacist with a code, and the researcher, research units and statistical analysts do not

know the content of the creams according to A and B codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

Street address

Golestan St , Jundi Shapur Ahvaz University of Medical Sciences

City

Ahvaz

Province

Khuzestan

Postal code

15794 - 61357

Approval date

2023-02-22, 1401/12/03

Ethics committee reference number

IR.AJUMS.REC.1401.556

Health conditions studied

1

Description of health condition studied

Candida vaginitis

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

Improvement of candidiasis signs

Timepoint

6-8 next days

Method of measurement

Examination and laboratory test and check list

Secondary outcomes

1

Description

Improvement of disease recurrence

Timepoint

40 days after the intervention

Method of measurement

Examination and laboratory test and checklist

Intervention groups

1

Description

Intervention group: grape seed cream, which will be made in Jundishapur Faculty of Pharmacy of Medical Sciences. To prepare medicine, 35 empty metal tubes of 50 grams with 2% grape seed cream will be prepared and filled with 50 grams of tube from Tolo Gostar Bukhara company/along with an applicator/one applicator should be used inside the vagina every night for seven days.

Category

Treatment - Drugs

2

Description

Control group: Clotrimazole vaginal cream 2%, which will be manufactured in Jundishapur Faculty of Pharmacy, along with an applicator, one applicator should be used inside the vagina every night for seven days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's Clinic affiliated to Ahvaz University of Medical Sciences

Full name of responsible person

Atefeh Ebrahimian

Street address

Women's Clinic affiliated to Ahvaz University of Medical Sciences(Women's Clinic of Imam Hospital, Razi, Golestan)

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Postal code

15794 - 61357

Phone

+98 916 040 5709

Email

ebrahimian127@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Naghme Yazdi

Street address

Jundishapur Medical Sciences, Golestan St

City

Ahvaz

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Phone

+98 916 040 5709

Email

naghme yazdi@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Jundishapur 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

Ahvaz University of Medical Sciences

Full name of responsible person

Atefeh Ebrahimian

Position

P.hD student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Naghmeh Yazdi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Ph.D Student

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

Undecided - It is not yet known if there will be 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

Yes - There is 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

Not applicable

Title and more details about the data/document

The reviewed data can be shared without mentioning the names of people

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Policymakers, researchers in academic and scientific institutions

Under which criteria data/document could be used

If you have an official letter from the scientific center

From where data/document is obtainable

Request from the printed magazine and indexed sites, request via e-mail of the project manager

What processes are involved for a request to access data/document

6 months after completing the study of the application, the data will be sent to the project manager, if the conditions are met, up to two months.

Comments