

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Randomize comparison of vaginal suppository containing cuminum cyminum essential oil with vaginal clotrimazole versus placebo vaginal suppository for vulvovaginal candidiasis treatment

Protocol summary

Study aim

Randomize comparison vaginal suppository containing cuminum cyminum essential oil with vaginal clotrimazole versus placebo vaginal suppository with vaginal clotrimazole for vulvovaginal candidiasis treatment

Design

This study is a single blind randomized parallel clinical trial

Settings and conduct

This study was performed in Imam Ali Educational and Medical Clinic in Shahrekord

Participants/Inclusion and exclusion criteria

Inclusion criteria :Diagnosis of candidiasis infection , women aged 18 to 50 years,be married, lack of sensitivity to cuminum cyminum herbal composition, lack of sensitivity to clotrimazol , signature of consent to participate in the study Exclusion criteria: pregnancy, lactation, menopause, underlying diseases,Allergy to cumin , Allergy to clotrimazole , forgetting one dose or more, the patient's unwillingness to continue treatment, menstruation during the study, abnormal uterine bleeding

Intervention groups

1. Cuminum cyminum essential oil suppository 2. Placebo suppository

Main outcome variables

Symptoms of candidal vaginitis (including itching, burning, vaginal redness, inflammation, vaginal discharge) 2. Symptoms of candidal vaginitis (including vaginal erythema, sticky white cheesy discharge, inflammation) 3. Possible side effects of drugs are compared in both therapies groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N11**

Registration date: **2021-10-10, 1400/07/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-10, 1400/07/18**

Update count: **0**

Registration date

2021-10-10, 1400/07/18

Registrant information

Name

MARYAM SHIEHMORTEZA

Name of organization / entity

AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-05, 1400/07/13

Expected recruitment end date

2021-11-11, 1400/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomize comparison of vaginal suppository containing

cuminum cyminum essential oil with vaginal clotrimazole versus placebo vaginal suppository for vulvovaginal candidiasis treatment

Public title

Randomize comparison of vaginal suppository containing cuminum cyminum essential oil with vaginal clotrimazole versus placebo vaginal suppository for vulvovaginal candidiasis treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18 - 50 years old Being married Signature of consent Diagnosis of candidiasis infection lack of sensitivity to cuminum cyminum or clotrimazole

Exclusion criteria:

Pregnancy lactation menopause Underlying diseases Menstruation during the study Forget one dose or more of medication Allergy to clotrimazole or cuminum cyminum suppository The patient's unwillingness to continue treatment Abnormal uterine bleeding

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

1

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

vaginal suppositories of cuminum cyminum and placebo were made by the researcher and were placed in aluminum foils individually , and everyone except the researcher was unaware of the composition of these drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University of Medical Sciences, Tehran, Pharmacy and Pharmaceutical Sciences branches

Street address

Azad University of Medical Sciences , Pharmacy and Pharmaceutical Sciences Branch , Yakhchal St., Gholhak, Dr. Shariati St. Tehran

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.IAU.PS.REC.1399.169

Health conditions studied

1

Description of health condition studied

Candidiasis vulvovaginitis

ICD-10 code

N77.1

ICD-10 code description

Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere

Primary outcomes

1

Description

Itching

Timepoint

Beginning of the study - 7 days after the start of the study

Method of measurement

Questionnaire - completing a checklist to evaluate the symptoms of candidal vaginitis and then compare the frequency of symptoms of candidal vaginitis within and between the two treatment groups

2

Description

discharge

Timepoint

Beginning of the study - 7 days after the start of the study

Method of measurement

Questionnaire

3

Description

Inflammation

Timepoint

Beginning of the study - 7 days after the start of the study

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: consist of 30 people who each receive a 2 gram vaginal suppository containing 0.1 cc of cuminum cyminum essential oil along with clotrimazole vaginal suppository daily for seven days (clotrimazole at night and cuminum cyminum suppository in the morning or noon). Cuminum cyminum suppository is based on polyethylene glycol 1000 and 4000 at the rate of 80% and 20% which is made in Tehran Azad University of Medical Sciences, Department of Pharmacy and Pharmaceutical Sciences. Participants will be explained how to use the drug at the beginning of the study .

Category

Treatment - Drugs

2

Description

Control group: Including 30 patients, each receiving a clotrimazole vaginal suppository and a placebo suppository daily for seven days (clotrimazole at night and placebo in the morning or at noon).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic in Shahrekord

Full name of responsible person

Fatemeh Sadat Abtahi

Street address

Unit 26, No. ,Nasser Tanha Alley, Berezenr St. , 45 metri Golshahr St,

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fatemehabtahi21@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Farshad Hashemian

Street address

Tehran islamic azad university of medical science, Khaghani street, Dr shariati street

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Web page address

http://iaups.iautmu.ac.ir/fa

Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad university

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

FatemehSadat Abtahi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Associate Professor

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Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable