Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

In vivo evaluation of vaginal suppository containing Corianderum sativum essential oil effect on the treatment of candidiasis infection

Protocol summary

Study aim
Evaluation of the effectiveness of vaginal suppository containing coriander seed essential oil in comparison with clotrimazole suppository in the treatment of vaginal candidiasis

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: women aged 18 to 50 years,. Marriage, lack of sensitivity to the plant compounds of coriander seeds, lack of sensitivity to clotrimazole, signing the consent form to participate in the study Exclusion criteria: pregnancy and lactation, menopause, underlying diseases, forgetting a dose or more, patient unwillingness to continue treatment, menstruation during the study, abnormal uterine bleeding

Intervention groups
1. Coriander seed suppository 2. Clotrimazole suppository

Main outcome variables
1) Symptoms of candidal vaginitis (including: itching, burning, vaginal redness, inflammation, vaginal discharge) 2) Symptoms of candidal vaginitis (including: vaginal erythema, white cheesy discharge and inflammation) 3) Possible side effects of drugs in both groups Therapies are compared.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150706023084N8**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **retrospective**
Last update: **2021-01-16, 1399/10/27**
Update count: **0**

Registration date
2021-01-16, 1399/10/27

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
2020-05-19, 1399/02/30

Expected recruitment end date
2020-08-20, 1399/05/30

Actual recruitment start date
2020-08-27, 1399/06/06

Actual recruitment end date
2020-12-20, 1399/09/30

Trial completion date
2020-12-27, 1399/10/07

Scientific title
In vivo evaluation of vaginal suppository containing Corianderum sativum essential oil effect on the treatment of candidiasis infection

Public title
In vivo evaluation of vaginal suppository containing corianderum sativum essential oil effect on the treatment of candidiasis infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 18-50 Diagnosis of candidiasis infection Signature of consent

Exclusion criteria:

Pregnancy, lactation, menopause, underlying diseases Sex during the study Forget a dose or more of medication Allergy to clotrimazole or coriander suppository The patient's unwillingness to continue treatment

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**

Actual sample size reached: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Vaginal suppositories of coriander seeds were made by the researcher and placed in aluminum foils individually, and clotrimazole suppositories were removed from the main cover and placed in the foil, and everyone except the researcher was unaware of the drug composition.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic azad tehran medical sciences university-pharmacy and pharmaceutical branches faculty

Street address

No.47, shahid Rajaee St ,Shahr-e kord

City

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Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815874459

Approval date

2019-12-24, 1398/10/03

Ethics committee reference number

IR.IAU.PS.REC.1398.293

Health conditions studied

1

Description of health condition studied

candidiasis vulvovaginit

ICD-10 code

N77.1

ICD-10 code description

Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere

Primary outcomes

1

Description

itching

Timepoint

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

Method of measurement

Questionnaire three-Complete 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 three

3

Description

inflammation

Timepoint

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

Method of measurement

Questionnaire three

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: consists of 30 people who each

receive a 2 g vaginal suppository containing 0.1 cc of coriander seed essential oil every night for seven nights. This suppository is based on polyethylene glycol 1000 and 4000 at the rate of 75% and 25% in Shahrekord University of Medical Sciences. Participants were explained how to use the drug at the beginning of the study.

Category

Treatment - Drugs

2

Description

Control group: including 30 people who each receive a 500 mg clotrimazole vaginal suppository every night for seven nights

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic in Shahrekord

Full name of responsible person

Rahil Mokhtarian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Farshad Hashemian

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Web page address

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Grant name

Grant code / Reference number

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

Yes

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

Rahil Mokhtarian

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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