

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The comparison effect of *Anethum graveolens* L. (dill) products on traditional medicine base with clotrimazole cream 1% on vaginal candidiasis.

Protocol summary

Summary

objective: comparing the effect of *Anethum graveolens* L. (Dill) vaginal cream with clotrimazole vaginal cream 1%(standard treatment) on vaginal candidiasis. Study Design: clinical trial; randomized (Blocked randomization); double-blind (creams with the same colour and tubes); single center. Study population: married women; Age group: between 18 to 65 years old; sample size: 105 patients. The main inclusion criteria: sign and symptoms of vulvovaginal candidiasis; with positive sniff test; and without complicated vaginal candidiasis on diagnosis of gynecologist. The main exclusion criteria: side effects or drug reaction. intervention: after vaginal candidiasis confirmation by sniff test, patient divided into 3 groups: 1)Essential oil of *Anethum graveolens* L. (Dill) vaginal cream (2%) and 2)standard treatment(clotrimazole vaginal cream (1%)) and 3) total extract of dill vaginal cream, and each patient use 1 applicator of vaginal cream a night. intervention time: 1 week. Physical examination, self report and vaginal smear measured before and 3 days after the end of interventions, will be compared in groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071929004N1**
Registration date: **2016-10-12, 1395/07/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-12, 1395/07/21

Registrant information

Name

Zohreh Sarhadinejhad

Name of organization / entity

Kerman University of Medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences.

Expected recruitment start date

2016-07-14, 1395/04/24

Expected recruitment end date

2017-03-14, 1395/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effect of *Anethum graveolens* L. (dill) products on traditional medicine base with clotrimazole cream 1% on vaginal candidiasis.

Public title

The effect of dill vaginal cream on treatment of candida vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: sign and symptoms of vulvovaginal candidiasis; married women; between 18 to 65 years old; with positive sniff test; without pregnancy, without breast feeding, without chronic disease such as (kidney ,liver, cardiac disease and diabetes), no existence of immunodeficiency nor complicated vaginal candidiasis on diagnosis of gynecologist and not using of systemic antibiotics and immunosuppressive drugs, or any vaginal drugs during the study and not using of systemic anti fungal drugs since 4 weeks ago. Exclusion criteria: side effects or drug reaction; pregnancy; menstruate; lack of patient's association.

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomised(Blocked randomization), case control,double blind , study in single field and control with standard treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Kerman University Of Medical Sciences

Street address

Kerman University Of Medical Sciences Paradise, Haftbagh freeway.

City

kerman

Postal code

Approval date

2016-07-13, 1395/04/23

Ethics committee reference number

IR.KMU.AH.REC.1395.15

Health conditions studied

1

Description of health condition studied

vulvovaginal Candidiasis

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

burning

Timepoint

at the beginning and 10 days after intervention

Method of measurement

Evaluation of clinical symptom's remission(burning) with VSQ (vulvovaginal symptom questionnaire)

2

Description

itching

Timepoint

at the beginning and 10 days after intervention

Method of measurement

Evauation of clinical symptom's remission (itching) with VSQ (vulvovaginal symptom questionnaire)

3

Description

vaginal discharge

Timepoint

at the beginning and 10 days after intervention

Method of measurement

Evaluation of clinical symptom's remission (vaginal discharge) with VSQ (vulvovaginal symptom questionnaire)

4

Description

Erithema

Timepoint

at the beginning and 10 days after intervention

Method of measurement

physical exam

5

Description

Edema

Timepoint

at the beginning and 10 days after intervention

Method of measurement

physical exam

Secondary outcomes

1

Description

sniff test outcome

Timepoint

at the beginning and 10 days after intervention

Method of measurement

vaginal smear

Intervention groups

1

Description

using one applicator of Essential oil of Anethum graveolens L. (Dill) vaginal cream (2%) every night for 7 nights.

Category

Treatment - Drugs

2

Description

using one applicator of Clotrimazole vaginal cream 1% every night for 7 nights .

Category

Treatment - Drugs

3

Description

using one applicator of total extract of dill vaginal cream (2%) every night for 7 nights .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology Clinic, Afzalipoor Hospital.

Full name of responsible person

Dr Zohreh Salari

Street address

Afzalipoor Hospital, Emam freeway

City

kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University Of Medical Sciences

Full name of responsible person

Kerman University Of Medical Sciences

Street address

Haftbagh freeway, Kerman University of Medical Sciences Paradise.

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kerman University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University Of Medical Sciences

Full name of responsible person

Zohreh Sarhadinejhad

Position

Iranian Traditional Medicine Assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty