

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect Of Vaginal Cream Glycyrrhiza Glabra On Improvement Of Symptoms Of Fungal Vulvovaginitis

Protocol summary

Summary

Objective: Determine Effect Of Vaginal Cream Glycyrrhiza Glabra On Improvement Of Symptoms Of Fungal Vulvo vaginitis. (2) Study Design: The sampling will be random and triple blind. This study will be placebo-controlled and single center. (3)How do : After receiving permission of ethics Committee, Research consul, and health affairs of Alborz University the researcher will attend at the selected health centers of Karaj city. A written informed consent will be obtained from the participants. Eligible women based on(4) including and excluding criteria will be selected. (5)intervention: Upon selection, they will be clinically examined and vaginal smears will be obtained. The smears will be sent to the laboratory for final diagnosis. Women with positive smear result will be allocated into two groups by random allocation. Group A will be treated with Clotrimazole vaginal cream as standard treatment and group B will be treated with vaginal cream licorice as (intervention group). Creams will be prepared in same shape, size, and color with symbols A or B in Shahid Beheshti University Laboratory. Eligible Participants will receive numbers 1-60 and will be randomly assigned in two groups with Microsoft Excel software (group A and B). Each subject will receive one of the creams and will use one applicator of the cream for 7 consecutive nights. The subjects are asked to contact with the researcher in case of side effects. The subjects are asked to attend at the health center for Checking Signs and symptoms (itching, cheesy secretion, painful intercourse, and dysuria, abnormal cervix) on day 7 . ((6)Main outcome variables)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031133008N1**

Registration date: **2017-04-03, 1396/01/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-03, 1396/01/14

Registrant information

Name

Neda Dodange Bala Khani

Name of organization / entity

Iran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 2885

Email address

neda.dod@gmail.com

Recruitment status

Recruitment complete

Funding source

Iran university of medical sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-08-06, 1396/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Of Vaginal Cream Glycyrrhiza Glabra On Improvement Of Symptoms Of Fungal Vulvovaginitis

Public title

Effect Of Vaginal Cream Glycyrrhiza Glabra On

Improvement Of Symptoms Of Fungal Vulvovaginitis

Purpose
Treatment

Inclusion/Exclusion criteria
Including criteria consisted of: Women at reproductive age of 15 to 45 years old ∴ married ∴ not being pregnant, menopause, and breast feeding ∴ having at least two symptoms of vaginal candidiasis in interview(observed and being confirmed by laboratory studies) ∴. Lack of chronic diseases such as disorders that weaken the immune system, blood pressure, and diabetes ∴. no use of Chemical and herbal antifungal drugs during the last two weeks ∴. not having other vaginal infection such as trichomonas vaginitis, bacterial and mixtures ∴. not using vaginal creams and suppositories during the 48 hours before starting of the study ∴. not participating in another research study, simultaneously with this study ∴. lack of allergy to licorice ∴. lack of use of broad-spectrum antibiotics and corticosteroids during the last two weeks for any medical proposes . Exclusion criteria consisted of: getting pregnant during the study ∴. allergy to licorice ∴. obligation to use of antibiotics for treatment of systemic infections other than vaginitis during the study ∴. Failure to adhere to the correct pattern of the treatment (forgetting the drug for more than one night).

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

School of Nursing and Midwifery, Yasemi Rashid
Street, Valiasr Street, Tehran

City

Tehran
Postal code
Approval date
2017-02-22, 1395/12/04
Ethics committee reference number
IR.IUMS.REC1395.9311373014

Health conditions studied

1

Description of health condition studied

candidal vulvovaginitis

ICD-10 code

N77.1

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

vaginal sores and lesions

Timepoint

1,7,14day

Method of measurement

positive,negetive

2

Description

vaginal redness

Timepoint

1,7,14day

Method of measurement

positive,negetive

3

Description

Itching genitals

Timepoint

1,7,14

Method of measurement

positive,negetive

4

Description

Dysuria

Timepoint

1,7,14 day

Method of measurement

positive,negetive

5

Description

cheesy white secretions

Timepoint

1,7,14day

Method of measurement

positive,negetive

6**Description**

Dyspareunia

Timepoint

1,7,14

Method of measurement

positive,negetive

7**Description**

Red vagina is with white discharge

Timepoint

1,7,14day

Method of measurement

positive,negetive

8**Description**

papulopustular damagesand

Timepoint

1,7,14

Method of measurement

positive,negetive

9**Description**

Abnormal cervical

Timepoint

1,7,14day

Method of measurement

positive,negetive

10**Description**

Laboratory evaluation

Timepoint

1,7,14day

Method of measurement

positive,negetive

Secondary outcomes**1****Description**

Licorice sensitivity

Timepoint

1,7,14

Method of measurement

positive,negetive

Intervention groups**1****Description**

vaginal cream licorice 50ml,one Applicator for7day

Category

Treatment - Drugs

2**Description**

vaginal cream clotrimazol 1%,one Applicator for7day

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Karaj Kamali Hospital Clinic affiliated Alborz University of Medical Sciences

Full name of responsible person

Poran Motalebzade

Street address

22 Bahman street, next to Azadegan park, Valad Abad public health centers

City

Karaj

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research of Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Javad Mousavi

Street address

Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran

City

Tehran

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 of Iran 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

Iran university of medical science

Full name of responsible person

Neda Dodange Balakhani

Position

Master student of midwifery

Other areas of specialty/work

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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