

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

A comparative study of the therapeutic effect of the propolis Vaginal cream and clotrimazole On Candida vulvovaginitis in reproductive aged women referring to shiraz gynecology clinics (2009)

Protocol summary

Summary

This study was carried out to compare the effect of Propolis vaginal cream with Clotrimazole on the treatment results of candidiasis vulvovaginitis . The subjects consisted of reproductive aged women (above 18 years and in premenopause age) who were not pregnant. From the viewpoint of clinical complaints and laboratory culture, all the patients were diagnosed to be afflicted. If the subjects were not considered patient according to the culturing were eliminated from the study. This clinical trial was conducted on 100 reproductive aged women for a period of 8 months .They were divided into two groups of 50 subjects(Clotrimazole and Propolis) by randomized allocation method. all the patients applied the drug once a day for 10 days only. The results were compared after 10 days of therapy and reculturing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805192325N1**

Registration date: **2010-05-25, 1389/03/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-25, 1389/03/04

Registrant information

Name

Mahsa Sadat Mousavi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2009-04-21, 1388/02/01

Expected recruitment end date

2009-12-22, 1388/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the therapeutic effect of the propolis Vaginal cream and clotrimazole On Candida vulvovaginitis in reproductive aged women referring to shiraz gynecology clinics (2009)

Public title

A comparative study of the therapeutic effect of the propolis Vaginal cream and clotrimazole On Candida vulvovaginitis in reproductive aged women referring to shiraz gynecology clinics (2009)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: willingness to participate, reproductive age (between 18 years and premenopause age).

Exclusion Criteria: pregnancy, breast feeding, using hormonal or immunosuppressive drugs, having sexually transmitted and autoimmune diseases or any other disease such as diabetes, allergy to Azole drugs, using antibiotics, antifungal compounds or vaginal drugs during two weeks prior to the study, suffering from recurrent vulvovaginitis (4 times or more during one year), using other supportive treatments like vaginal douch at the time of drug application, negative culture

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz Zand St.

City

Shiraz

Postal code

Approval date

2009-10-05, 1388/07/13

Ethics committee reference number

ct 88-4556

Health conditions studied

1

Description of health condition studied

Candidia Vulvovaginitis

ICD-10 code

N76.0

ICD-10 code description

acute vaginitis

Primary outcomes

1

Description

therapeutic results of Candida vulvovaginitis

Timepoint

10 days

Method of measurement

culture

Secondary outcomes

empty

Intervention groups

1

Description

Propolis vaginal cream 10%, one applicator per day, for 10 days

Category

Treatment - Drugs

2

Description

Clotrimazole vaginal cream 10%, one applicator per day, for 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology clinic of zeinabieh hospital

Full name of responsible person

Street address

Zeinabieh hospital, Khatoon Sq., Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Mohammad Hosein Dabbagh Manesh

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Zand St., Shiraz

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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
 Vice chancellor for Research, Shiraz 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

Fatemeh (PBUH) college of Nursing and Midwifery
 Shiraz University of Medical Sciences

Full name of responsible person

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Position

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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