Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparing the effect of methanol extract of Myrtus communis and clotrimazole on treatment of vaginal candidiasis

Protocol summary

Summary

Objective: The present study was designated to compare the antifungal activities of clotrimazole and methanol extract M. communis in the treatment of Vulvovaginal candidiasis in- vivo. Methods: A double-blind, randomized, clinical trial was conducted in health clinics of Dezful, in the southwest of Iran . Of 276 women admitted, 70 eligible women with Vulvovaginal candidiasis (according symptoms, pH of vagina, and vaginal culture) were randomly assigned into two treatment groups. There was no significant difference between the two groups regarding characteristic of age, parity, contraceptive method and educational level. In group 1, 35 women were assigned to receive 5 gr. of vaginal clotrimazole and in group 2, 35 women were assigned to receive 5 gr. vaginal cream of methanol extract the M.communis 1% for 5 days. Symptoms and vaginal cultures at 2 weeks and 8 weeks after treatment were examined.

General information

Acronym

VVC

IRCT registration information

IRCT registration number: **IRCT2013012312250N1**

Registration date: **2013-03-07, 1391/12/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-07, 1391/12/17

Registrant information

Name

Fahimeh Yousefinezhad

Name of organization / entity

Islamic Azad Unversity, Branch Dezful

Country

Iran (Islamic Republic of)

Phone

+98 64 1626 2417

Email address

yousefi@iaud.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences

Expected recruitment start date

2006-02-03, 1384/11/14

Expected recruitment end date

2007-03-08, 1385/12/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of methanol extract of Myrtus communis and clotrimazole on treatment of vaginal candidiasis

Public title

Efficacy of medical plants on Vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Aged 20-30 years; clinical signs and symptoms of Candida vaginitis, pH vaginal (4-4.5) wet smear and culture positive. Exclusion criteria: Pregnant and lactating women; who have multiple sexual partners; diabetes; women with history of chronic Vulvar vaginal Candidiasis (at least 4 times in one year); use of immunosuppressive drugs; current use of oral combined contraceptive pills (OCPs); use of vaginal or oral anti-

fungal in a month later and exposure of other Vaginitis.

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahvaz University of Medical Sciences

Street address
Golestan High way

City
Ahvaz

Postal code
1579461357

Approval date
2005-06-05, 1384/03/15

Ethics committee reference number
84u84

Health conditions studied

1

Description of health condition studied
Vulvovaginal candidiasis

ICD-10 code
n77

ICD-10 code description
Vulvovaginal ulceration and inflammation in diseases classified elsewhere

Primary outcomes

1

Description
Pruritus

Timepoint
Before treatment , 2 and 8 weeks after treatment

Method of measurement
Vsual Analog Scale for severty symptom

2

Description
Vaginal discharge

Timepoint
Before treatment , 2 and 8 weeks after treatment

Method of measurement
Visual Analog Scale for severty symptom-wet smear-culture

3

Description
Vulvar Erythematic

Timepoint
Before treatment , 2 and 8 weeks after treatment

Method of measurement
Visual Analog Scale for severty symptom-wet smear-culture

4

Description
dysuria

Timepoint
Before treatment , 2 and 8 weeks after treatment

Method of measurement
Visual Analog Scale for severty symptom

5

Description
Vulvar Edema

Timepoint
Beftore treatment , 2 and 8 weeks after treatment

Method of measurement
Visual Analog Scale for severty symptom-wet test and cultuer

6

Description
Disparonia

Timepoint
Before treatment, 2 and 8 weeks after treatment

Method of measurement
Visual Analog Scale for severty symptom

Secondary outcomes

empty

Intervention groups

1

Description
In intervation gruop:Cream vaginal 1%of Myrtus communis methanol extract was administered an applicator (5 gr) for five consecutive nights
Category
Treatment - Drugs

2

Description
in control group: vaginal cream of clotrimazole1% was administered an applicator (5 gr) for five consecutive nights
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Health center no. 1
Full name of responsible person
Street address
Enghlab st.
City
Dezful

2

Recruitment center
Name of recruitment center
Health center no. 3
Full name of responsible person
Street address
Komial St.
City
Dezful

3

Recruitment center
Name of recruitment center
Health center no. 5
Full name of responsible person
Ghazi Blvd.
Street address
City
Dezful

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Asadi Zaker Marziyeh
Street address
Nursing and midwifery school of Ahvaz University of Medical Sciences
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University Medical sciences
Full name of responsible person
Poorandokht Afshary
Position
master degree
Other areas of specialty/work
Street address
Nursing and Midwifery faculty
City
Ahvaz
Postal code
Phone
+98 61 1336 7544
Fax
Email
f_afshary@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University, Dezful Branch
Full name of responsible person
Fahimeh Yousefinezhad
Position
Master Degree
Other areas of specialty/work
Street address
213, Mesam st.
City
Dezful
Postal code
6461975591

Phone
+98 54 1222 5220
Fax
Email
f_yousefynezhad@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University, Dezful Branch
Full name of responsible person
Fahimeh Yousefi nezhad
Position
Master Degree
Other areas of specialty/work
Street address
213, Mesam st.
City
Dezful
Postal code
6461975591

Phone
+98 64 1222 6220
Fax
Email
f_yousefynezhad@yahoo.com
Web page address

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