Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing calendula officinalis and clotrimazole for treatment of candida vaginitis: a randomized controlled trial

Protocol summary

Summary

The aim of this triple-blind trial is to compare the effect of calendula officinalis with clotrimazole on treatment of candida vaginitis. 124 women aged 18-45 years with known candidiasis and no other vaginal infections will be allocated into two intervention groups using block randomization with allocation ratio 1:1 and block sizes of 4 and 6, determined with a computerized program. The creams will be prepared in industrial pharmacy laboratory of Tabriz University of Medical Sciences. A person not involved in the recruitment and data collection will put the identical calendula officinalis and clotrimazole creams into sequentially numbered sealed opaque packs to conceal allocation sequence and maintain blinding. The participants will use the calendula officinalis or clotrimazole cream vaginally, one applicator every night for 7 nights. They will be recommended to comply with health issues and do not use douching, other vaginal drugs and also herbal and systemic drugs during study period. We will ask participants to come back 15-10 days and 35-30 days after initiation of treatment for evaluation of treatment and relapse, respectively. The infection diagnosis, and evaluation of treatment and relapse will be based on clinical symptoms, assessment of vaginal pH, direct observation and culture. The self-administered female sexual function index (FSFI) will be also completed at baseline and 35-30 days after intervention to assess the intervention effects on sexual function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309253706N20**
Registration date: **2014-03-03, 1392/12/12**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-03-03, 1392/12/12

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-03-03, 1392/12/12

Expected recruitment end date

2014-07-03, 1393/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing calendula officinalis and clotrimazole for treatment of candida vaginitis: a randomized controlled trial

Public title

Effect of calendula officinalis on treatment of candida vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: aged 18 to 45 years old; being married; diagnosis of candidiasis; single sexual partner; no history of allergy to drugs and plants; being literate; giving consent to participate in the study. Exclusion criteria: having any known chronic disease; use of any antibiotics and corticosteroids in the past two weeks; receiving antifungal drugs in the past 4 weeks; currently taking oral contraceptives; existence of other vaginal infections; any sores or lumps at the cervix; experience of severe stress over the past month; known Pregnancy; lactation; currently use of other herbal medicines; participation at another trial.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Participants and people involved in data collection, laboratory investigation and data analysis will be blinded of the subjects' group assignment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences, Research Deputy

Street address
3rd floor, Centeral building No 2, Tabriz University of Medical Sciences, Golgasht st., Tabriz

City
Tabriz

Postal code

Approval date
2014-02-10, 1392/11/21

Ethics committee reference number
92184

Health conditions studied

1

Description of health condition studied
Candida vaginitis

ICD-10 code
B37.3+

ICD-10 code description
Candidiasis of vulva and vagina

Primary outcomes

1

Description
Response to the treatment

Timepoint
10-15 days after the initiation of intervention

Method of measurement
Assessment of vaginal pH, direct observation, secretion culture

2

Description
Relapse of the infection

Timepoint
30-35 days after the initiation of intervention

Method of measurement
Assessment of vaginal pH, direct observation, secretion culture

Secondary outcomes

1

Description
Sexual function score

Timepoint
Before intervention, 30-35 days after the initation of therapy

Method of measurement
Female sexual function Index (FSFI)

2

Description
Adverse events

Timepoint
10-15 days after the initation of therapy

Method of measurement
Self-report

3

Description
Clinical complaints

Timepoint
Baseline, 10-15 and 30-35 days after initiation of intervention

Method of measurement

Self-report

4

Description
Client satisfaction
Timepoint
10-15 and 30-35 days after the initation of intervention
Method of measurement
Self-report

Intervention groups

1

Description
Intervention I: vaginal use of Calendula Officinalis cream, one aplicator every night for 7 nights
Category
Treatment - Drugs

2

Description
Intervention II: Vaginal use of Clotrimazole cream, one aplicator every night for 7 nights
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Elnaz Saffari
Street address
City
Tabriz

2

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Elnaz Saffari
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad-Reza Rashidi
Street address
Research Deputy, 3rd floor,Centeral building No 2 , Tabriz University of Medical Sciences, Golgasht st., Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Tabriz 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
Midwifery Department, Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences
Full name of responsible person
Elnaz Saffari
Position
MSc student in midwifery
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Kousar Dormitory, South Shariati Ave, Tabriz
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences
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Position
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Other areas of specialty/work
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Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

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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