

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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, Central 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 initiation of therapy

Method of measurement

Female sexual function Index (FSFI)

2

Description

Adverse events

Timepoint

10-15 days after the initiation 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 initiation of intervention

Method of measurement

Self-report

Intervention groups

1

Description

Intervention I: vaginal use of Calendula Officinalis cream, one applicator every night for 7 nights

Category

Treatment - Drugs

2

Description

Intervention II: Vaginal use of Clotrimazole cream, one applicator 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

City

Tabriz

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, Central 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

Other areas of specialty/work

Street address

Kousar Dormitory, South Shariati Ave, Tabriz

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elnazsafari82@yahoo.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tabriz University of
Medical Sciences

Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

Associate Professor, PhD in Reproductive Health

Other areas of specialty/work

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Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

Associate Professor, PhD in Reproductive Health

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