

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of the effectiveness of salvia officianalis plant, clotrimazole alone and in combination on the improvement and recurrence of candida vaginitis

Protocol summary

Summary

Aims: the effectiveness of salvia officianalis plant, clotrimazole alone and in combination on the improvement and recurrence of candida vaginitis. Study design: a triple blind randomized controlled trial (the assessor, participants, and data analyzer will be unaware of the type of intervention given to every participant). Study population: women with symptoms of candida vaginalis who will refer to health center of Tabriz University of medical sciences in year 2017. Inclusion criteria: clinical signs of candidal vaginitis; Positive tests for direct observation; Positive discharge cultures, married women. Exclusion criteria: pregnant and lactating and Menopause women; use of vaginal medication in the last two weeks; suffering from autoimmune diseases; Having menstrual bleeding or bleeding between two monthly cycles during a visit; trichomoniasis and Gardnerella positive; occurrence of symptoms of drug allergy. Sample size and studied intervention: 111 persons, three groups of 37 people included: recipient of 400 mg vaginal Salvia officinalis tablet and clotrimazol placebo, recipient of 400 mg vaginal Salvia officinalis tablet and 100 mg vaginal Clotrimazole tablet, recipient of 100 mg vaginal clotrimazol tablet and Salvia officinalis placebo. The intervention time: one week. Study outcome: negative clinical and laboratory findings and clinical complaints one week and 12 week after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020227311N4**

Registration date: **2017-07-23, 1396/05/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-23, 1396/05/01

Registrant information

Name

Behnaz Sadeghzadeh Oskoue

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3479 0364

Email address

sadeghzadehb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for education, Tabriz University of Medical Sciences

Expected recruitment start date

2017-07-11, 1396/04/20

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of salvia officianalis plant, clotrimazole alone and in combination on the improvement and recurrence of candida vaginitis

Public title

Comparison of the effectiveness of salvia officinalis plant, clotrimazole alone and in combination on the improvement and recurrence of candida vaginitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: clinical signs of candidal vaginitis; Positive tests for direct observation; Positive discharge cultures; married; 15-49 years old; Reading and writing literacy herself or a family member; Willingness to participate in the study and Possibility to visit the clinic at the requested time; Having a phone call. Exclusion criteria: pregnant and lactating and Menopause women; use of antibiotics and medications that suppress the immune system (corticosteroids) and the use of vaginal medication in the last two weeks; suffering from autoimmune diseases; chronic disease and hypothyroidism...; Having menstrual bleeding or bleeding between two monthly cycles during a visit; trichomoniasis and Gardnerella positive; use of contraceptive pills and high carbohydrate intake; occurrence of symptoms of drug allergy.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **111**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
This study is a triple blind randomized controlled trial using 3 and 6 blocks of 1: 1: 1 ratio in three groups with 37 members.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences,

Golgasht Street, Azadi Avenue
City
Tabriz
Postal code
Approval date
2017-06-28, 1396/04/07
Ethics committee reference number
IR.TBZMED.REC.1396.251

Health conditions studied

1

Description of health condition studied

Candidiasis of vulva and vagina

ICD-10 code

N77.1

ICD-10 code description

Vaginitis, vulvitis and vulvovaginitis in infectious and parasitic diseases classified elsewhere

Primary outcomes

1

Description

Determine clinical and laboratory results

Timepoint

one and 12 week after treatment

Method of measurement

By signs checklist, wet test, Gram colorin and culture

Secondary outcomes

1

Description

Clinical complaints of patients

Timepoint

One and 12 weeks after starting treatment

Method of measurement

Clinical symptom checklist

Intervention groups

1

Description

The women in intervention group will recipient of 400 mg vaginal Salvia officinalis tablet and clotrimazol placebo once a day for seven day

Category

Treatment - Drugs

2

Description

The women in intervention group will recipient of 400 mg vaginal Salvia officinalis tablet and 100 mg vaginal Clotrimazole tablet once a day for seven day

Category

Treatment - Drugs

3

Description

women in control group will recipient of 100 mg tablet vaginal clotrimazol and clotrimazol placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

AlzahraTherapeutic Educational Center

Full name of responsible person

Fatemeh Ahangari, MSc Student of Midwifery

Street address

City

Tabriz

2

Recruitment center

Name of recruitment center

Taleghani Therapeutic Educational Center

Full name of responsible person

Fatemeh Ahangari, MSc Student of Midwifery

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue

City

Tabriz

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, 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

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

fatemeh ahangari

Position

MSc Student of Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Behnaz Sadeghzadeh Oskuei

Position

Assistente Professor, PhD Biology of Reproductive Medicine

Other areas of specialty/work

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Full name of responsible person

fatemeh ahangari

Position

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Other areas of specialty/work**Street address**

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Tabriz

Postal code**Phone**

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Fax**Email****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