Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of Cinnamon zeylanicum capsules and Clotrimazole vaginal cream on the treatment and relapse of Candida Vaginitis in Tehran.

Protocol summary

Summary

The purpose of this randomized double blind study will be to determine the effects of Cinnamon zeylanicum capsules and Clotrimazole vaginal cream on the treatment and relapse of Candida vaginitis in Tehran. 120 patients will be randomly divided into two groups: intervention (capsules Cinnamon and Clotrimazole vaginal cream) and control (placebo and Clotrimazole vaginal cream). The patients use (500 mg capsules of cinnamon three times a day (morning, noon, night) with clotrimazole vaginal cream1 % One applicator of cream will be used at bed time for one week) and the other group (400 mg capsules of starch powder three times a day with clotrimazole vaginal cream1%) over one weeks. Patients will be followed 3-4 days after the beginning of the treatment and will be returned in 4-3 days after the end of the treatment for reexamination and evaluation of the clinical signs and sampling and the next 14 days for the recurrence evaluation and sampling

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206104317N7**
Registration date: **2012-07-26, 1391/05/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-07-26, 1391/05/05

Registrant information

Name

Fatemeh Nahidi

Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services

Country

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Recruitment status

Recruitment complete

Funding source

Pharmaceutical Sciences Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Expected recruitment start date

2012-05-11, 1391/02/22

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Cinnamon zeylanicum capsules and Clotrimazole vaginal cream on the treatment and relapse of Candida Vaginitis in Tehran.

Public title

The effects of Cinnamon zeylanicum capsules and Clotrimazole vaginal cream on the treatment and relapse of Candida Vaginitis in Tehran.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being Iranian; Being married ; Age between 15 or 45; Positive wet smear of vaginal discharge; Not being pregnancy, lactation and menopausal period; Not having any vaginal bleeding; Not having chorionic disease (diabetes, HIV,...); Women that

hadn’t history of using antibiotic for 2 weeks before; Women that don’t use oral contraceptive pills; Not being overweight (Body Mass Index>29); Not having intercourse and vaginal douching during the last24 hours; Not using any antifungal drugs, for 2 weeks before the study; Not using vaginal cream for last 48 hours before the study; Not having allergy with herbal drugs Exclusion criteria: Having Trichomoniasis and bacterial vaginosis; Having allergy with herbal drugs; Having gastric ulcer

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shaheed Beheshti University of Medical Sciences and Health Services

Street address

Shaheed Beheshti University of Medical Sciences and Health Services, Beside Taleghani Hospital, Evin, Tabnak St., Shaheed Chamran Avenue, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-04-30, 1391/02/11

Ethics committee reference number

777-114-01-1390

Health conditions studied

1

Description of health condition studied

Candida vaginitis

ICD-10 code

N77.1

ICD-10 code description

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

2

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

Treatment

Timepoint

Before treatment -3-4 days after the beginning of treatment - 14-days aftertreatment

Method of measurement

Information form

2

Description

Recurrence

Timepoint

14 days after treatment and 8 weeks after treatment for the recurrence

Method of measurement

Wet smear and Culture

Secondary outcomes

empty

Intervention groups

1

Description

The patients in intervdntion group use 500 mg capsules of cinnamon three times a day (morning, noon, night) with clotrimazole vaginal cream1 %. One applicator of cream was used at bed time for one week

Category

Treatment - Drugs

2

Description

The patients in placebo group use 400 mg capsules of starch powder three times a day(morning, noon, night) with clotrimazole vaginal cream1%.One applicator of cream use at bed time for one week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Hossein Medical & Educational Center

Full name of responsible person
Fatemeh Nahidi and Roya Najafi

Street address
Madani Ave, Tehran, Iran

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Pharmaceutical Sciences Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Ira

Full name of responsible person
DR.Seyed Farsad Hosseini Shirazi

Street address
Vali-e-asr Ave., Southwest of Niayesh junction, P.O.Box:14155-3817

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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
Pharmaceutical Sciences Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Ira

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
Shahid Beheshtii University of Medical Sciences

Full name of responsible person
Fatemeh Nahidi

Position
Faculty member of Shahid Beheshti University of Medical Sciences , MSc in Midwifery and PhD candidat

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