

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the effect of Clotrimazol vaginal cream and coconut oil vaginal cream in women with vaginal candidiasis

Protocol summary

Summary

This study is interventional and experimental clinical trial study was done to compare the effect of coconut oil vaginal cream with clotrimazol vaginal cream in the treatment of women with vaginal candida infection. Inclusion criteria: signs and symptoms of Candida vaginitis, positive direct smear of vaginal discharge Exclusion criteria: pregnant women, low compliance, recurrent Candida vaginitis (4 or more Candida vaginitis in a year), consumption of immunosuppressive drug or widespread antibiotics, history of diabetes, heart disease, using other vaginal creams or suppositories during the study period, consumption of systemic antifungal drugs during 2 weeks prior to the study, presence of non-candidal vaginitis, consumption of oral contraceptives. The study was triple blind (A blind clinical trial for the investigator, statistics analyst, and patients) and was conducted the method table of random numbers on 60 married women aged 45-15 years with clinical signs of the disease and laboratory confirmation. The participants were randomly divided to two treatment groups (coconut oil or clotrimazol). One applicator of the creams was applied nightly for a week and 2-7 days after completion of treatment, examinations and tests were performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042521934N1**

Registration date: **2016-08-24, 1395/06/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-24, 1395/06/03

Registrant information

Name

Sedigheh Sheidaei

Name of organization / entity

Mashhad University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

sheidaeis931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University Of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Clotrimazol vaginal cream and coconut oil vaginal cream in women with vaginal candidiasis

Public title

Comparison of the effect of Clotrimazol vaginal cream and coconut oil vaginal cream in women with vaginal candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: signs and symptoms of Candida

vaginitis, positive direct smear of vaginal discharge
Exclusion criteria: pregnant women, low compliance, recurrent Candida vaginitis (4 or more Candida vaginitis in a year), consumption of immunosuppressive drug or widespread antibiotics, history of diabetes, heart disease, using other vaginal creams or suppositories during the study period, consumption of systemic antifungal drugs during 2 weeks prior to the study, presence of non-candidal vaginitis, consumption of oral contraceptives.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University Of Medical Sciences

Street address

Mashhad, Deputy of Research and Technology, After Hoveyze Cinema, Daneshgah street, Mashhad University of Medical Science.

City

Mashhad

Postal code

00989138813944

Approval date

2016-06-15, 1395/03/26

Ethics committee reference number

IR.MUMS.REC.1395.157

Health conditions studied**1****Description of health condition studied**

Candidiasis of vulva and vagina

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes**1****Description**

Compleet remission

Timepoint

2 to 7 days after treatment

Method of measurement

Evauation of clinical symptom's remission with questionnaire

Secondary outcomes**1****Description**

Vaginal culture results

Timepoint

Before intervention and 2 to 7 days after intervention

Method of measurement

Vaginal smear

Intervention groups**1****Description**

Intervention group Coconut oil, vaginal Cream, one applicator every night, for one Week.

Category

Treatment - Drugs

2**Description**

Control group Clotrimazol, vaginal Cream, one applicator every night, for one week.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem (AJ) Hospital

Full name of responsible person

Sedigheh Sheidaei

Street address

Mashhad, Shariati Square (Taghi Abad), Ahmad Abad Street, Ghaem Educational, Research and Medical

center

City

Mashhad

2

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Sedigheh Sheidaei

Street address

Mashhad, Ebne Sina Street, Emam Reza Square

City

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3

Recruitment center

Name of recruitment center

Omolbanin Hospital

Full name of responsible person

Sedigheh Sheidaei

Street address

Mashhad, Behjat street, at the corner of Behjat 16

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Science

Full name of responsible person

Dr Saieed Eslami

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Mashhad, Deputy of Research and Technology, After Hoveyze Cinema, Daneshgah street, Mashhad University of Medical Science

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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

Vice chancellor for research, Mashhad University of Medical Science

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

Mashhad University of Medical Sciences

Full name of responsible person

Farzane Jafar Nejad

Position

Master of Midwifery

Other areas of specialty/work

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Graduate Student Midwives

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Phone**Fax****Email**

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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