

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of Nigella sativa versus Clotrimazole in remedy of Vaginal Candidiasis

Protocol summary

Summary

Objective: comparison of Nigella sativa versus Clotrimazole in remedy of Vaginal Candidiasis. Design: Randomize, Single blind, Interventional, Without placebo. Inclusion criteria: Married women between 18-49 years old; Patients who had a single sexual partner and they themselves were the only sexual partner of their respective spouse; Women who had not used antibiotics, immunosuppressive drugs, vaginal drugs 14 days before the study; Patients who were not at pregnancy or breast-feeding stage and did not consume alcohol. Exclusion criteria: patients with pregnancy, diabetes and immunodeficiency. Target sample size: 100 People. Primary outcome measure: Vaginal wall secretion, In the first visit and 7 to 14 days after first visit, By using speculum. Intervention group: Nigella sativa suppository, 2%, once a day for a week. Control group: Clotrimazole suppository, 100 ml, once a day for a week

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111920001N1**
Registration date: **2014-12-30, 1393/10/09**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-30, 1393/10/09

Registrant information

Name

Nafiseh Saghafi

Name of organization / entity

Ghaem Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 4499

Email address

saghafin@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2006-06-01, 1385/03/11

Expected recruitment end date

2007-03-01, 1385/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Nigella sativa versus Clotrimazole in remedy of Vaginal Candidiasis

Public title

Treatment of Vaginal Candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Married women between 18-49 years old; Patients who had a single sexual partner and they themselves were the only sexual partner of their respective spouse; Women who had not used antibiotics, immunosuppressive drugs, or vaginal drugs 14 days before the study; Patients who were not at pregnancy or breast-feeding stage and did not consume alcohol. Exclusion criteria: patients with pregnancy, diabetes and immunodeficiency.

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Vice chancellor for research, Mashhad University of Medical Sciences

Street address

Ghoreishi building, Daneshgah St, Vice chancellor of research, Mashhad

City

Mashhad

Postal code**Approval date**

2005-08-17, 1384/05/26

Ethics committee reference number

84138

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

Vaginal Candidiasis

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

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

Vaginal wall secretion

Timepoint

In the first visit and 7 to 14 days after first visit

Method of measurement

By using speculum

Secondary outcomes

empty

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

Intervention group: Nigella sativa suppository, 2%, once a day for a week.

Category

Treatment - Drugs

2**Description**

Control group: Clotrimazole suppository, 100 ml, once a day for a week.

Category

Treatment - Drugs

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

Ghaem Hospital

Full name of responsible person

Nafiseh Saghafi

Street address

Ghaem Hospital, Ahmadabad St, Mashhad

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mashhad University of medical Sciences

Full name of responsible person

Mohammad Ramezani

Street address

Ghoreishi building, Daneshgah St, Vice chancellor of research, Mashhad

City

Mashhad

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 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**

Ghaem Hospital

Full name of responsible person

Nafiseh Saghafi

Position

Assistant Professor

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Ghaem Hospital

Full name of responsible person

Nafiseh Saghafi

Position

Assistant professor

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

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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