

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the therapeutic effect of Honey and Nigella sativa (Dosin) vaginal cream and Clotrimazole vaginal cream in treatment Candida Vulvovaginitis

Protocol summary

Study aim

Evaluation of the therapeutic effect of honey and Nigella Sativa (Dosin) vaginal cream with Clotrimazole vaginal cream in treatment Candida Vulvovaginitis.

Design

The study is conducted as a randomized triple-blind study .The sample size for comparison of two groups determine 84 women are infected with Candidal vulvovaginitis.

Settings and conduct

The study is conducted in Baharloo Hospital in the city of Tehran. Clotrimazole vaginal cream and and honey and Nigella Sativa (Dosin) vaginal cream are packaged similarly, and is marked "B" and "A". Samples, researcher, and statistical analysis are unaware of the content of cream. Therefore, the present study is conducted as a Triple-blind study

Participants/Inclusion and exclusion criteria

Exclusion criteria include :being at age of 18 to 49 years old, Not being pregnancy,Not being lactation, Not Having Allergy to Honey or Nigella Sativa or Clotrimazole,Not being period, Not using vaginal cream and vaginal douch and for last 48 hours before the study, Not using vaginal cream and vaginal douch and for last 48 hours before the study,Not Having recurrent Candida vaginitis (4 or more Candida vaginitis in a year), Not Having of history of curettage, Hysterosalpingography and uterine surgery in the last two weeks, No history of receiving blood or chemotherapy in a recent month,Having of signs and symptoms of Candida vaginitis, positive direct smear and culther of vaginal discharge, Exclusion criteria include:Not Agreeing to Participate in the Study, The use of antibiotics to treat non-vaginitis systemic infections during treatment, Participation at another trial, Pregnancy in the study time table

Intervention groups

One group (honey and Nigella Sativa (Dosin) vaginal

cream); Another group (Clotrimazole vaginal cream)

Main outcome variables

Outcome of culture of vaginal discharge; fungal symptoms

General information

Reason for update

Describe how to randomize

Acronym

IRCT registration information

IRCT registration number: **IRCT20190711044176N1**

Registration date: **2019-07-26, 1398/05/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-12, 1398/07/20**

Update count: **1**

Registration date

2019-07-26, 1398/05/04

Registrant information

Name

Seyedeh Tahereh Mirmolaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

mirmolaei@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of Honey and Nigella sativa (Dosin) vaginal cream and Clotrimazole vaginal cream in treatment Candida Vulvovaginitis

Public title

Therapeutic effects of Dosin (Nigella sativa and Honey) vaginal Cream on Candida Vulvovaginitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women were married and aged between 18-49 years old
Not being pregnancy
Not being lactation
Not Having Allergy to Honey or Nigella Sativa or Clotrimazole
Not being period
Not using vaginal cream and vaginal douch and for last 48 hours before the study
Not Having of history of diabetes and deficiency of immune system
Not Having recurrent Candida vaginitis (4 or more Candida vaginitis in a year)
Not Having of history of curettage, Hysterosalpingography and uterine surgery in the last two weeks
No history of receiving blood or chemotherapy in a recent month
Having of signs and symptoms of Candida vaginitis, positive direct smear and culther of vaginal discharge

Exclusion criteria:

Not Agreeing to Participate in the Study
The use of antibiotics to treat non-vaginitis systemic infections during treatment
Participation at another trial
Pregnancy in the study time table

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

the research units were divided into two groups of intervention and control, using four-dimensional permutation blocks. First, 6 possible blocks are listed (AABB, ABAB, BBAA, BABA, ABBA, BAAB) and each block is assigned a number from one to six. Then they are randomly assigned to the experimental and control groups using a random number table from one to six, followed by a block based on the number chosen. This will continue until the sample size is complete.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient is asked to fill out the letter of consent to participate in the study and simple randomly is assigned to two groups, case and control. Clotrimazole Vaginal cream and Honey and Nigella Sativa Vaginal cream are packaged similarly and is marked "A" and "B" by a pharmacist. Creams are applied each night as an applicator (5 g) inside the vagina for 7 nights. Samples, research group, and statistical analysis are unaware of the content of cream. the present study is conducted as a Triple-blind study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The ethics Committee of the Faculty of Nursing and Midwifery, Tehran University of Medical Science

Street address

PO Box 6459, Dr Mirkhani St. (Eastern Nusrat), Tohid Square

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2019-07-09, 1398/04/18

Ethics committee reference number

IR.TUMS.FNM.REC.1398.074

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

Candida VulvoVaginitis

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina (N77.1*)

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

Symptoms and signs of Candida Vulvovaginitis

Timepoint

Before intervention, 6-10 day after treatment

Method of measurement

Questionnaire, Microscopic evaluation, Secretion culture, Measurements Of Ph

Secondary outcomes

1

Description

Improve Of Candida Vulvovaginitis

Timepoint

6-10 Day After Treatment

Method of measurement

Questionnaire, culther

Intervention groups

1

Description

Intervention group: Intervention group: honey and Nigella Sativa "Dositin" vaginal cream each night as an applicator inside the vagina for 7 nights.

Category

Treatment - Drugs

2

Description

Control group: Control group: Clotrimazole vaginal cream each night as an applicator inside the vagina for 7 nights.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharloo Hospital Gynecology Clinic

Full name of responsible person

Masoumeh Norouzi

Street address

Baharloo Hospital - Behdari.st - Railway.sq

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4215

Email

Norouzi7378@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeian

Street address

No23, Valiasr Avenue, Dameshgh Street

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۷۱

Phone

+98 21 8163 3685

Email

norouzi7378@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Norouzi

Position

Master of Midwifery Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

PO Box 6459, Dr Mirkhani St. (Eastern Nusrat), Tohid Square

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4215

Email

norouzi7378@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Seyedeh Tahereh Mirmolaei

Position

Phd in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

East Nosrat Avenue, Towhid square, Nursing and Midwifery Faculty, Tehran University Of Medical Science

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4215

Email

mirmolaei@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Norouzi

Position

Student Master Of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Nursing and Midwifery Faculty, Tehran University of Medical Sciences, East Nosrat Avenue, Towhid Square

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4215

Email

norouzi7378@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available