

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of Salvia Officinalis vaginal cream and clotrimazole in the treatment of vaginal candidiasis in Diabetes women

Protocol summary

Study aim

Comparison of Salvia Officinalis vaginal cream and clotrimazole in the treatment of vaginal candidiasis in Diabetic women

Design

Clinical trial with a control group, parallel group, non-randomized, and accessible method

Settings and conduct

Emam Reza, Ommolbanin hospital /After confirmation of the laboratory, two groups consume vaginal cream

Participants/Inclusion and exclusion criteria

Diabetic women with candida vaginitis, having a score of at least 3 of the total score of symptoms of vaginal candida infection in examination and observation / acute stress

Intervention groups

Diabetic women with candida vaginitis include two groups: Salvia Officinalis vaginal cream and clotrimazole who consume one night for 7 nights.

Main outcome variables

Improve vaginal candidiasis symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190221042787N1**

Registration date: **2019-05-12, 1398/02/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-12, 1398/02/22**

Update count: **0**

Registration date

2019-05-12, 1398/02/22

Registrant information

Name

Raha Pirouzmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

pirouzmandr961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-10-12, 1398/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Salvia Officinalis vaginal cream and clotrimazole in the treatment of vaginal candidiasis in Diabetes women

Public title

The effect of salvia officinalis vaginal cream on vaginitis in diabetic women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Written consent for participation in the study Have at least reading and writing skills Resident of Mashhad city Married and having more than 15 years of ages Prove diabetes by examining a patient's case No history of clotrimazole susceptibility No history of allergy to the lamina family No pregnancy Non-Lactation Lack of

menopause No IUD and Not using hormonal contraceptive methods Non-use of special medication within the last two weeks Failure to catch vaginal candida infection more than 4 times a year Lack of a menstrual period or any vaginal bleeding Having a score of at least 3 of the total score of symptoms and symptoms of vaginal candida infection during examination and observation In the examination of the absence of genital tract infections Positive vaginal discharge culture of a candidate Not having a medical condition other than diabetes Lack of acute and new stress in the last 8 weeks No addiction or hookah smoking Having a single partner Failure to perform curettage,Histro Salpango Graphy. surgery in the last two weeks Not getting blood and Chemotherapy in the last 4 weeks No use of antifungals to treat Vaginal infection in the last two weeks Not having sexually transmitted infections in the last month

Exclusion criteria:

Refusal to participate in research by research unit Having sensitivity to the medicine given Having acute and severe stress during treatment Use of certain medication during treatment The use of an anti fungal drug with a given drug period monthly or abnormal bleeding during the study Lack of vaginal cream over one night Antibiotic therapy during treatment Use of aromatic and sanitary materials for washing the vagina Use of herbal remedy or other anti fungal medication (topical or oral) with the medicine given

Age

From **15 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not 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

Faculty of Nursing and Midwifery, Ibn Sina Avenue,Daneshgah Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2019-03-02, 1397/12/11

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.089

Health conditions studied

1

Description of health condition studied

vaginal candidiasis Diabetes women

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

Vaginal Candidiasis in Diabetes Women

Timepoint

A week± 24 hours

Method of measurement

Culture Discharg In laboratory

Secondary outcomes

1

Description

Itching

Timepoint

Before treatment, a week ± 24 hours after treatment

Method of measurement

Patient's biography

2

Description

Erythema

Timepoint

Before treatment, a week ± 24 hours after treatment

Method of measurement

Clinical examination, observation and patient history

3

Description

Irritation

Timepoint

Before treatment, a week \pm 24 hours after treatment
Method of measurement
patient history

4

Description
Painful intercourse
Timepoint
Before treatment, a week \pm 24 hours after treatment
Method of measurement
patient history

5

Description
The result of vaginal discharge culture
Timepoint
Before treatment, a week \pm 24 hours after treatment
Method of measurement
vaginal discharge culture

Intervention groups

1

Description
Intervention group: Salvia Officinalis Vaginal Cream 2% ,an applicator every night for 7 nights
Category
Treatment - Drugs

2

Description
Control group: clotrimazole vaginal cream1% ,an applicator every night for 7 nights
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Raha Pirouzmand
Street address
Imam Reza Hospital Squire - Imam Reza Hospital
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2

Recruitment center
Name of recruitment center
Ommolbanin Hospital
Full name of responsible person
Raha Pirouzmand
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Ayatolah Bahjat16- Ayatolah Bahjat Street-Zarrineh Crossroads
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Tafaghodi Mohsen
Street address
Deputy of Research and Technology of the University- Mashhad University of Medical Sciences,Daneshgah 18 Street
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Fax
+98 51 3882 3251
Email
tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

Postal code

9137913199

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Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Raha Pirouzmand

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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

Mashhad University of Medical Sciences

Full name of responsible person

Raha Pirouzmand

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, Ibn Sina Avenue, Daneshgah Avenue

City

Mashhad

Province

Razavi Khorasan

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