

# 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  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913199  
**Phone**  
+98 51 3859 7313  
**Fax**  
**Email**  
pirouzmandr961@mums.ac.ir

**Web page address**  
<http://emamreza.mums.ac.ir/index.php>

#### 2

**Recruitment center**  
**Name of recruitment center**  
Ommolbanin Hospital  
**Full name of responsible person**  
Raha Pirouzmand  
**Street address**  
Ayatolah Bahjat16- Ayatolah Bahjat Street-Zarrineh Crossroads  
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**Email**  
pirouzmandr961@mums.ac.ir  
**Web page address**  
<http://woman.mums.ac.ir/index.php/contact-us>

### 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  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913199  
**Phone**  
+98 51 3882 3255  
**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**

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**Email**

pirouzmandr961@mums.ac.ir

**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

**Street address**

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

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**Province**

Razavi Khorasan

**Postal code**

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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**

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**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