

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessing the response to co- treatment of single dose fluconazole with vaginal lactobacillus in diabetic patients with vaginal candidiasis

#### Protocol summary

##### Study aim

The present study aims to compare the effects of fluconazole(150mg) with vaginal(lacto flora fem) probiotic capsules with fluconazole(150mg) on vulvovaginal candidiasis.

##### Design

Randomized, parallel groups trial with blinding

##### Settings and conduct

The study is done in health care center in Matini Hospital in partnership with Diabetes center. patients and medical personnel are kept blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: married non pregnant women aged 18-45 years old; absence of menstruation at the time of attendance; not using vaginal medications, antibiotics , immunosuppressive drugs and exogenous hormones such as oral contraceptives since 2 weeks before starting the research; not having intercourse or using vaginal douche within the last 24 hours; diabetic patients; verification of vulvovaginal candidiasis resulted clinical symptoms and KOH positive samples and cultivation. Exclusion criteria: allergic reactions to fluconazole, Lacto Flora Fem; pregnancy during therapy; compulsion to use antibiotics or other anti fungal drugs.

##### Intervention groups

Intervention group: vaginal probiotic capsules(Lacto Flora Fem) are prescribed for 14 nights plus fluconazole (150mg) single dose orally. Control group : vaginal placebo are prescribed for 14 nights plus fluconazole(150mg)single dose orally.

##### Main outcome variables

Vaginal candidiasis symptoms

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180612040071N1**

Registration date: **2018-08-16, 1397/05/25**

Registration timing: **prospective**

Last update: **2018-08-16, 1397/05/25**

Update count: **0**

##### Registration date

2018-08-16, 1397/05/25

##### Registrant information

###### Name

Parisa Mamivand

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 3616 3625

###### Email address

Parisa.mamivand00@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-06, 1398/06/15

##### Expected recruitment end date

2021-02-24, 1399/12/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing the response to co- treatment of single dose fluconazole with vaginal lactobacillus in diabetic patients with vaginal candidiasis

##### Public title

Survey of response to co- treatment of single dose

fluconazole with vaginal lactobacillus in diabetic patients with vaginal candidiasis

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

married women aged 18-45 years old non pregnant diabetic no diagnosed medical disease such as auto immune diseases, by asking the patient diagnosis of candidal vulvovaginitis by clinical symptoms, positive KOH test and cultivation absence of menstruation at the time of attendance not using vaginal medications, antibiotics , immunosuppressive drugs and exogenous hormones such as oral contraceptives since 2 weeks before starting the research not having intercourse or using vaginal douche within the last 24 hours

#### **Exclusion criteria:**

allergic reactions to fluconazole or lacto flora fem pregnancy during therapy use antibiotics or other anti fungal drugs

### **Age**

From **18 years** old to **50 years** old

### **Gender**

Female

### **Phase**

3

### **Groups that have been masked**

- Participant
- Care provider

### **Sample size**

Target sample size: **130**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Patients with inclusion criteria are randomized by using 4&6 blocks method. Randomization list is prepared before starting the intervention. Patients go under special treatment based on randomize allocation. Patient division conducts by the clerk of the clinic who is blinded to the intervention.

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

patients and therapist are blinded to the type of treatment due to similarity of the placebo and Lacto Flora Fem in shape.drug form and route of administration are similar. During assessment gynecologist will be blinded to the treatment.

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

## **1**

### **Ethics committee**

#### **Name of ethics committee**

Ethics committee of Kashan University of Medical Scinces and Health Services

#### **Street address**

5th of Qotb -e Ravandi Blvd. P.O.Box: 8715988141, Kashan, IRAN

#### **City**

kashan

#### **Province**

Isfahan

#### **Postal code**

8715988141

### **Approval date**

2017-05-31, 1396/03/10

### **Ethics committee reference number**

IR.KAUMs.REC.139640

## **Health conditions studied**

## **1**

### **Description of health condition studied**

Candidal Vulvovaginitis

### **ICD-10 code**

B37.3

### **ICD-10 code description**

Candidiasis of vulva and vagina

## **Primary outcomes**

## **1**

### **Description**

Vaginal candidiasis symptoms

### **Timepoint**

1 month (30dayes ) after the use of probiotics or placebo

### **Method of measurement**

questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

## **1**

### **Description**

intervention group: Oral single dose Fluconazol (150mg) treatment with vaginal Lacto Flora Fem for 14 nights

### **Category**

Treatment - Drugs

## **2**

### **Description**

Control group: : Oral single dose Fluconazol (150mg) treatment with vaginal Lacto Flora Fem for 14 nights

### **Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Matini hospital

**Full name of responsible person**

Zahra Vahedipoor

**Street address**

Amir kabir BLV , Kashan, IRAN

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr Hamidi

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parisa.mamivand00@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Mehdi Nazeri

**Position**

Assistant Professor of Medical mycology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Parasitology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

we express only clinical and laboratory outcomes

**When the data will become available and for how long**

Information will be published as article and final report

**To whom data/document is available**

Access limitation is not considered

**Under which criteria data/document could be used**

The final report and article will be available for other researchers

**From where data/document is obtainable**

Library of Kashan University of Medical Sciences

**What processes are involved for a request to access data/document**

Direct referral to the library

**Comments**