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 , immonosupressive 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)

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+98 21 3616 3625

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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 , immonosupressive 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

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kashan

Province

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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
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Amir kabir BLV , Kashan, IRAN
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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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