Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Effect of oral and vaginal administration probiotic in treatment of women with vaginal candidiasis

Protocol summary

Study aim
The compare the effects of fluconazole(150mg) with vaginal(lactovag) and oral(lactofem) probiotic capsules with Fluconazole(150mg) on vulvovaginal candidiasis.

Design
A randomized, double blinded controlled clinical trial with a parallel group design of 80 patients, enrolled between July 2017and April 2019, and followed for 30-35 days.

Settings and conduct
Imam Reza Gynecology Clinic and Naghavi Hospital of Kashan

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- married women aged 18-45 years old 2- None pregnant absence of menstruation 3- Not using vaginal medications, antibiotics, immonosupressive drugs and exogenous hormones such as oral contraceptives since 2 weeks before starting the research 4- Not having intercourse or using vaginal douche within the last 24hours 5- Absence of any diagnose medical disease such as diabetis and other auto immune diseases 6- Vulvovaginal candidiasis based on clinical symptoms and laboratory finding Exclusion criteria: 1- Allergic reactions to fluconazole, lactovag and lactofem 2- Pregnancy during therapy 3- Compulsion to use antibiotics or other anti fungal drugs.

Intervention groups
Patients with vulvovaginal Candidiasis are randomly assigned to two groups. Group 1 will be treated with vaginal and oral probiotics for 14 and 28 days, respectively, with one oral fluconazole (150 mg), and in cases of recurrent vaginitis, receive three fluconazoles once every 72 hours. Group 2 will be treated with vaginal and oral placebo for 14 and 28 days, respectively, with one oral fluconazole (150 mg), and in recurrent vaginitis, three fluconazole will be treated every 72 hours.Patients are evaluated after 35-30 days based on clinical symptoms and laboratory findings.

Main outcome variables
Clinical symptoms: itching, burning, discharge, and dyspareunia Laboratory findings: Direct smear and positive culture

General information

Reason for update
Increase the number and time of sampling.

Acronym

IRCT registration information
IRCT registration number: **IRCT2016090529710N1**
Registration date: **2016-09-30, 1395/07/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-09, 1398/08/18**
Update count: **1**

Registration date
2016-09-30, 1395/07/09

Registrant information

Name
Mehdi Nazeri

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source
1-Vice chancellor for Research & Technology, Kashan University of Medical Sciences; 2- zist takhmir company

Expected recruitment start date
2016-07-20, 1395/04/30

Expected recruitment end date

2018-03-27, 1397/01/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral and vaginal administration probiotic in treatment of women with vaginal candidiasis

Public title

Effect of oral and vaginal administration probiotic in treatment of women with vaginal candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

married women aged 18-45 years old none pregnant 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 24hours absence of any diagnose medical disease such as diabetis and other auto immune diseases, by asking the patient not having intercourse or using vaginal douche within the last 24 hours verification of vulvovaginal candidiasis resulted clinical symptoms and KOH positive smear and culture

Exclusion criteria:

allergic reactions to fluconazole, lactovag and lactofem pregnancy during therapy compulsion to use antibiotics or other anti fungal drugs.

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by simple method and using random numbers generated by computer software (Stat Trek software). In this method the computer selects random numbers. with consideration of numbers, the two groups are randomized.

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo will be used to achieve participants,Care provider and investigators will be masking. The researchers and patients will be concealed until the final analyses by a trained staff.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

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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Approval date

2016-07-10, 1395/04/20

Ethics committee reference number

IR.KAUMS.REC.1395.30

Health conditions studied

1

Description of health condition studied

Vulvovaginal Candidiasis

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

Vaginal candidiasis symptoms

Timepoint

35-30 days after starting probiotic or placebo treatment

Method of measurement

questionnaire

Secondary outcomes

1

Description

Dirct smear and Culture

Timepoint

30-30 days after starting treatment with fluconazole and probiotic or placebo

Method of measurement

culture and direct smear

Intervention groups

1

Description

Oral Fluconazol treatment with Oral probiotic capsules containing Lactobacillus acidophilus,Lactobacillus plantarum,Lactobacillus fermentum, Lactobacillus gasseri 1×10 9 colony are known as lactofem for once a day for 27 days(4 weeks) plus Vaginal probiotic capsules containing Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus gasseri, Lactobacillus plantarum 1×10 9colony are known as lacto Vage for once every night for 14days(4 weeks)

Category

Treatment - Drugs

2

Description

Oral Fluconazol treatment with Oral placebo for once a day for 27 days(4 weeks) plus Vaginal placebo for once every night for 14days(4 weeks)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi hospital

Full name of responsible person

Dr. Zahra Vahedipoor

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Shahid Rajaei Street, P.O.Box: 87137/43444, Kashan, IRAN

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2

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Scinces and Health Services

Full name of responsible person

Dr. Hamidi

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Grant name

Vice Chancellor of Research & Technology of Kashan University of Medical Scinces

Grant code / Reference number

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

Yes

Title of funding source

Kashan University of Medical Scinces and Health Services

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

Department of Medical Parasitology and Mycology, Medical faculty, kashan university of medical scien

Full name of responsible person
Mehdi Nazeri

Position
Assistant Professor of Medical mycology

Latest degree
Ph.D.

Other areas of specialty/work
Mycology

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Person responsible for updating data

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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