Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparing the effect of probiotic and fluconazole in treatment and recurrent of vaginal candidiasis: A three-blind randomised controlled trial

Protocol summary

Study aim
Comparing the effect of probiotic and fluconazole in treatment and recurrent of vaginal candidiasis

Design
This is a three-blind randomized controlled trial with two intervention groups that will be performed on 80 women of reproductive age with candida vaginitis. Eligible individuals are placed in groups randomly using a computer random table through random blocking of four and six and clients in a ratio of 1: 1 allocation to two groups (recipient of fluconazole tablets and probiotic placebo and recipient of probiotic capsules and Fluconazole placebo)

Settings and conduct
People with candida vaginitis referred to Taleghani and Zahrai gynecological clinics in Tabriz are randomly assigned to two groups of drug recipients.In order to Allocation Concealement, the drugs will be placed in numbered consecutive frosted jars and delivered to participants in the order in which they enter the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Married women aged 15-49 -Positive culture of secretions from the candidate's point of view-Be literate-Willingness to participate in the study and the possibility of visiting the clinic at the requested times-Having a contact phone -Being a resident of Tabriz Exclusion criteria: Pregnancy, lactation and menopause -Use of antibiotics and immunosuppressive drugs and use of vaginal drugs during the last two weeks -Currently taking oral contraceptives-Having autoimmune diseases -Having chronic diseases such as diabetes, anemia, hypothyroidism, etc. - Having menstrual bleeding during the visit of the participant -Abnormal uterine bleeding-Non-candida vaginitis -Recurrent vulvovaginitis -Symptoms of drug allergy-Consumption of any probiotic product

Intervention groups
Receiver of fluconazole tablets and probiotic placebo
Receiver of probiotic capsules and fluconazole placebo

Main outcome variables
Negative culture on day 35-40 and 60-65

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110826007418N5**
Registration date: **2021-03-03, 1399/12/13**
Registration timing: **prospective**

Last update: **2021-03-03, 1399/12/13**
Update count: **0**

Registration date
2021-03-03, 1399/12/13

Registrant information

Name
Parisa Yavarikia

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-10, 1399/12/20

Expected recruitment end date
2021-06-10, 1400/03/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of probiotic and fluconazole in treatment and recurrent of vaginal candidiasis: A three-blind randomised controlled trial

Public title

omparing the effect of probiotic and fluconazole in treatment and recurrent of vaginal candidiasis: A three-blind randomised controlled trial

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Married women aged 15-49 (lack of virginity) Positive culture of discharge from the candidate's point of view Be literate Willingness to participate in the study and the possibility of visiting the clinic at the requested times Having a contact phone Living in the city of Tabriz

Exclusion criteria:

Pregnancy, lactation and menopause Use of antibiotics and immunosuppressive drugs (corticosteroids, etc.) and use of vaginal drugs during the last two weeks Currently taking oral contraceptives according to the participant Having autoimmune diseases Having chronic diseases such as diabetes, anemia, hypothyroidism, etc. Having menstrual bleeding during the visit of the participant Abnormal uterine bleeding Non-candidal vaginitis Recurrent vulvovaginitis (four or more cases during the year) Symptoms of drug allergy Consumption of any probiotic product (supplements, food, etc.)

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Placement of individuals in groups is done randomly using a computer random table through random blocking of four and six and clients in a ratio of 1: 1 allocation to two groups (recipient of fluconazole tablets and probiotic placebo and recipient of probiotic capsules and Fluconazole placebo) Similar glasses are prepared in terms of appearance, the contents of which are also not visible, and each glass contains contains 30 capsules and one tablet and includes two types: the first type contains one pink fluconazole tablet 150mg and 30 capsules 500mg of probiotic placebo, and the second contains The second type contains 30 500mg probiotic capsules and one 150mg fluconazole placebo tablet. Fluconazole placebo is pink. Random allocation will be provided by the person not involved in the sampling. In order to Allocation Concealement, the drugs will be placed in numbered consecutive frosted jars and delivered to participants in the order in which they enter the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Similar glasses are prepared in terms of appearance, the contents of which are also not visible, and each glass contains contains 30 capsules and one tablet and includes two types: the first type contains one pink fluconazole tablet 150mg and 30 capsules 500mg of probiotic placebo, and the second contains The second type contains 30 500mg probiotic capsules and one 150mg fluconazole placebo tablet. Fluconazole placebo is pink. Random allocation will be provided by the person not involved in the sampling. In order to Allocation Concealement, the drugs will be placed in numbered consecutive frosted jars and delivered to participants in the order in which they enter the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Nursing & Midwifery Faculty, South Shariati Streetwifery, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2020-12-07, 1399/09/17

Ethics committee reference number

IR.TBZMED.REC.1399.848

Health conditions studied

1

Description of health condition studied

vaginal candidiasis

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

Frequency of negative culture in two intervention groups

Timepoint

Day 40-35 after starting treatment and day 65-60 after starting treatment

Method of measurement

Cultivation in the laboratory

Secondary outcomes

1

Description

Patients complain of foul-smelling discharge

Timepoint

Day 35-40 and day 60-65 after starting treatment

Method of measurement

Questionnaire of signs and symptoms of the person

2

Description

Patients complain of itching

Timepoint

Day 35-40 and day 60-65 after starting treatment

Method of measurement

Questionnaire of signs and symptoms of the person

3

Description

Patients complain of burning

Timepoint

Day 35-40 and day 60-65 after starting treatment

Method of measurement

Questionnaire of signs and symptoms of the person

4

Description

Patients complain of inflammation and vaginal erythema

Timepoint

Day 35-40 and day 60-65 after starting treatment

Method of measurement

Questionnaire of signs and symptoms of the person

5

Description

Patients complain of frequent urination

Timepoint

Day 35-40 and day 60-65 after starting treatment

Method of measurement

Questionnaire of signs and symptoms of the person

6

Description

Patients complain of urinary incontinence

Timepoint

Day 35-40 and day 60-65 after starting treatment

Method of measurement

Questionnaire of signs and symptoms of the person

7

Description

Patients complain of pain during intercourse

Timepoint

Day 35-40 and day 60-65 after starting treatment

Method of measurement

Questionnaire of signs and symptoms of the person

8

Description

Vaginal pH

Timepoint

Day 35-40 and day 60-65 after starting treatment

Method of measurement

Checklist for recording observations and clinical results

9

Description

Satisfaction rate

Timepoint

Day 35-40 after starting treatment

Method of measurement

Personal Satisfaction Questionnaire

10

Description

Adverse events during the intervention

Timepoint

Any time of study

Method of measurement

Checklist for side effects

Intervention groups

1

Description

First intervention group :Take one dose of 150 mg fluconazole tablets and then a daily 500 mg probiotic placebo capsule (containing starch and made by the researcher) for one month. Day 12-15 Phone follow-up will be done and in addition to emphasizing the regular use of prescribed drugs and other instructions, the candidiasis symptoms questionnaire will be completed by phone. The first and second follow-up (in person) is 35-40 days and 60-65 days after the start of treatment. From the pH meter paper, the vaginal pH is determined and recorded in a checklist, and a sample will be taken from the vaginal canal for laboratory culture.

Category

Treatment - Drugs

2

Description
The second intervention group: Take one dose of 150 mg placebo fluconazole tablets (which contain starch and will be made by the researcher) and then take a daily probiotic capsule containing containing Lactobacillus acidophilus daily at a dose of □10□^9 CFU/g CFU / g for one month (Probiotic powder is prepared in the order of the researcher from Hansen company in 25 gram packages and is poured into the capsule by the relevant personnel in Tabriz School of Pharmacy and Medical Sciences.). Day 12-15 Phone follow-up will be done and in addition to emphasizing the regular use of prescribed drugs and other instructions, the candidiasis symptoms questionnaire will be completed by phone. The first and second follow-up (in person) is 35-40 days and 60-65 days after the start of treatment. From the pH meter paper, the vaginal pH is determined and recorded in a checklist, and a sample will be taken from the vaginal canal for laboratory culture.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Zahra Mollazadeh Narestan
Street address
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
Research department, third floor, central construction number 2, Tabriz Medical Science University, Golgasht Street, Azadi Avenue
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rashidi@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Zahra Mollazadeh Narestan
Position
MSc student in Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery

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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
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data sets are to be shared after deidentified IPD.
When the data will become available and for how long
Data will become available 6 months after publication.
To whom data/document is available
data is available for people working in academic institutions.
Under which criteria data/document could be used
Obligation to observe ethics.
From where data/document is obtainable
E-mail: yavarikiap@tbzmed.ac.ir
What processes are involved for a request to access data/document
A request to access data/document will be respond during one week.
Comments