Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparing the Effects of Mycozin and Clotrimazole 1% on Vaginal Candidiasis: a Triple Blinded Randomized Controlled Trial

Protocol summary

Study aim
Comparing the effects of Mycozin and Clotrimazole 1% on vaginal candidiasis

Design
A triple-blind clinical trial, phase 3 on 126 patients. Randomization will done using Random Allocation Software (RAS) through blocked randomization method.

Settings and conduct
This research is a triple-blind randomized clinical trial (participant, researcher, outcome assessor and data analyst will be blinded) with the aim of comparing the effect of mycozin with clotrimazole 1% vaginal cream on the treatment of vaginal candidiasis will be done in married women aged 18-45 years old referring to the Al-Zahra educational-therapeutic hospital in Tabriz city.

Participants/Inclusion and exclusion criteria
Inclusion criteria:18-45 years; married; having reading and writing literacy; lackof allergy to herbal medicines and compounds containing azole; suffering from Candida vaginitis Exclusion criteria: Suffering from chronic diseases; taking antibiotics, corticosteroids and oral contraceptives; menstruation at the time of study; having a wound or mass in the cervix; having severe mental stress during the last three months; pregnancy or breastfeeding at the time of the study; taking other drugs to treat vaginitis; having recurrent vulvovaginitis; abnormal uterine bleeding.

Intervention groups
Intervention group 1 will use Mycozin vaginal cream at bedtime for one week. Intervention group 2 will use Clotrimazole 1% vaginal cream at bedtime for one week.

Main outcome variables
Negative culture in terms of vaginal candidiasis; Signs and symptoms of vaginal candidiasis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N77**
Registration date: **2023-05-20, 1402/02/30**
Registration timing: **prospective**

Last update: **2023-05-20, 1402/02/30**
Update count: **0**

Registration date
2023-05-20, 1402/02/30

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-31, 1402/03/10

Expected recruitment end date
2023-11-01, 1402/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the Effects of Mycozin and Clotrimazole 1% on Vaginal Candidiasis: a Triple Blinded Randomized Controlled Trial

Public title
Comparing the Effects of Mycozin and Clotrimazole on Vaginal Candidiasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-45 years married Being literate in reading and writing Lack of allergy to herbal medicines Suffering from candidal vaginitis
Exclusion criteria:
Suffering from chronic diseases such as diabetes, AIDS, immune system disorders, depression, etc. currently, according to the participant's statement Taking antibiotics and corticosteroids during the last two weeks according to the participant's statement Menstruation at the time of study Current use of oral contraceptives as reported by the participant The presence of a wound or mass in the cervix when viewed with a speculum Existence of severe mental stress during the last three months, such as the death of first-degree relatives Presence of pregnancy or breastfeeding at the time of study Taking other drugs to treat vaginitis Having recurrent vulvovaginitis (more than four times per year) Abnormal uterine bleeding
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **126**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants will be allocated randomly into two groups receiving mycosin vaginal cream and clotrimazole vaginal cream 1% using Random Allocation Software (RAS) through four and six blocks and with a ratio of 1:1 (40 people in each group) . The type of allocation will be written on paper and placed in consecutively numbered opaque envelopes (Allocation Concealment). The envelopes will be opened in order by a person not involved in sampling.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The participants, researcher and data analyst will be blinded completely in this study. Mycozin and Clotrimazole will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in the research.
Placebo
Not 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
Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue
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Tabriz
Province
East Azarbaijan
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5138947977
Approval date
2023-05-08, 1402/02/18
Ethics committee reference number
IR.TBZMED.REC.1402.112

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 clinical symptoms (smell, quantity, consistency, color and appearance of vaginal secretions, vaginal inflammation, appearance of cervix)
Timepoint
Before the intervention and 10 to 15 days after the intervention
Method of measurement
Clinical examination by the researcher and clinical symptoms checklist

2

Description
Frequency of patient complaints (secretions, dysuria, frequency, itching, itching during intercourse, pain in the

lower abdomen, burning sensation during intercourse, and dyspareunia)

Timepoint

Before the intervention and 10 to 15 days after the intervention

Method of measurement

Stated by the participants and complaints checklist

3

Description

Frequency of laboratory symptoms (negative smear and culture of vaginal secretions)

Timepoint

Before the intervention and 10 to 15 days after the intervention

Method of measurement

Sampling will be done with a sterile cotton swab from the posterior fornix of the vagina, and we will dip the swab inside the blood culture tubes and gently shake it inside the solution until the sample dissolves in it. Incubation will be at 37 degrees for 2 to 4 hours, and a drop of the contents of the tube solution will be transferred on a slide. We examine the slide under the microscope with high and low magnification. Germ tube formation test is a quick test to identify Candida albicans and differentiate it from other yeasts.

Secondary outcomes

1

Description

PH of vaginal secretions

Timepoint

Before the intervention and 10 to 15 days after the intervention

Method of measurement

PH paper

2

Description

Satisfaction with the treatment

Timepoint

10 to 15 days after the intervention

Method of measurement

Satisfaction questionnaire

3

Description

Side events

Timepoint

10 to 15 days after the intervention

Method of measurement

Side events checklist

Intervention groups

1

Description

Intervention group 1 will use Mycozin vaginal cream at bedtime for one week.

Category

Treatment - Drugs

2

Description

Intervention group 2 will use Clotrimazole 1% vaginal cream at bedtime for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra educational hospital

Full name of responsible person

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Sponsors / Funding sources

1

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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
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
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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