

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of the clinical efficacy of the vaginal-topical clotrimazole and oral lactobacillus in treatment of vulvovaginal candidiasis

Protocol summary

Summary

Among the patients who have the inclusion criteria and accepted being in this study we will select two groups. Group 1: oral lactobacillus acidophilus plus topical & vaginal clotrimazole. Group 2: oral placebo plus topical & vaginal clotrimazole. Seven days and 30 days after treatment we will evaluate therapeutic response considering clinical signs and symptoms

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901303756N1**

Registration date: **2011-07-24, 1390/05/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-24, 1390/05/02

Registrant information

Name

Tarlan Hamidehkhoo

Name of organization / entity

Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Science

Expected recruitment start date

2011-03-03, 1389/12/12

Expected recruitment end date

2011-07-21, 1390/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the clinical efficacy of the vaginal-topical clotrimazole and oral lactobacillus in treatment of vulvovaginal candidiasis

Public title

Evaluation of the effectiveness of oral lactobacillus acidophilus on treatment of women's yeast infections

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: married ladies with sign and symptoms of vulvovaginal candidiasis Exclusion criteria: pregnancy; breast feeding; side effects of the drug and lack of patient's cooperation in the study

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor For Research, Ahvaz University of Medical Sciences

Street address

Golestan blvd, Daneshgah squar

City

Ahvaz

Postal code

Approval date

2011-02-26, 1389/12/07

Ethics committee reference number

ETH101

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

Compelet remission

Timepoint

7days and 30 days after treatment

Method of measurement

Evauation of clinical symptom's remission with questionnaire

2

Description

Relapse of the symptoms

Timepoint

30 days after treatment

Method of measurement

Evaluation of relapsing symptoms after primary remission with questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The patients in intervension group will receive oral probiotic twice daily for 1 month, added to conventional treatment :vaginal-topical clotrimazole for 1 or 2weeks in acute or chronic types respectively .

Category

Treatment - Drugs

2

Description

The patients in control group will recieve vaginal-topical clotrimazole for 1week or 2weeks in acute or chronic types respectively + placebo capsules twice daily for 1month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini hospital of the Ahvaz

Full name of responsible person

Tarlan hamidehkhoo, Resident of Obstetrics & Gyenecology

Street address

Emam Khomeini hospital,ahvaziyan street,azadegan avenue

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University Of Medical Sciences

Full name of responsible person

Dr. Mostafa Feghhi, Vice-Chancellor For Research

Street address

Vice-Chancellor For Research, Jundishapour University Of Medical Sciences, Golestan Blvd , Daneshgah square

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Ahvaz University Of Medical Scienses
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty