

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effect of Micosin vaginal cream compared to Miconazole vaginal cream for the treatment of mycotic vaginitis

Protocol summary

Summary

The purpose of this clinical trial study was to compare the effects of Micosin vaginal cream with Miconazole vaginal cream for the treatment of mycotic vaginitis. This clinical trial was conducted on 120 women in their reproductive age who were diagnosed with candida vaginitis through clinical examinations and laboratory tests. Using randomized allocation method, the subjects were divided into two groups of 60 people. The participants in the first group were treated by Miconazole, while subjects in the second group were prescribed Micosin. Patients in both groups were asked to apply the drug once a day for seven consecutive days. After seven days of therapy, patients were re-examined through clinical and laboratory tests to compare the results. Inclusion criteria: women with Symptoms of Candida vaginitis infection in reproductive age. Exclusion criteria: any history of taking antibiotics or immunosuppressive drugs or vaginal medications during the four weeks prior to the start of the study; diagnosis with cervicitis; suffering from candida vaginitis for more than 3 times a year; pelvic inflammatory disease; pregnancy or menopause; patients with high risk conditions (such as diabetes, anemia, obesity, overt autoimmune disease, coagulation disorders); history of allergic reaction to garlic or cream of vaginal azole class; improper application of the medication; refusal to pay follow-up visits; personal decision by patients not to participate in the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120715697N1**

Registration date: **2014-03-02, 1392/12/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-02, 1392/12/11

Registrant information

Name

Shiva Alizadeh

Name of organization / entity

Islamic Azad university of rasht

Country

Iran (Islamic Republic of)

Phone

+98 13 1422 2154

Email address

gelayolalizadeh@iaurasht.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Islamic Azad University of Rasht

Expected recruitment start date

2013-05-07, 1392/02/17

Expected recruitment end date

2013-09-12, 1392/06/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Micosin vaginal cream compared to Miconazole vaginal cream for the treatment of mycotic vaginitis

Public title

Effect of Micosin vaginal cream compared to Miconazole vaginal cream for the treatment of mycotic vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women with Symptoms of Candida vaginitis infection in reproductive age. Exclusion criteria: any history of taking antibiotics or immunosuppressive drugs or vaginal medications during the four weeks prior to the start of the study; diagnosis with cervicitis; suffering from candida vaginitis for more than 3 times a year; pelvic inflammatory disease; pregnancy or menopause; patients with high risk conditions (such as diabetes, anemia, obesity, overt autoimmune disease, coagulation disorders); history of allergic reaction to garlic or cream of vaginal azole class; improper application of the medication; refusal to pay follow-up visits; personal decision by patients not to participate in the study.

Age

From **16 years** old to **49 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University of Rasht

Street address

Department of Midwifery; Islamic Azad University of Rasht; Pole Taleshan; Rasht; Guilan; Iran

City

Rasht

Postal code

413353516

Approval date

2013-02-26, 1391/12/08

Ethics committee reference number

17-16-5-741

Health conditions studied

1

Description of health condition studied

candidiasis vaginitis

ICD-10 code

B37.3+

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

Improvement of candidiasis vaginitis signs

Timepoint

One week after treatment

Method of measurement

cheak list; examination; wet mount; fungial culture.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Using one applicator of Micosin vaginal cream every night for 7 nights.

Category

Treatment - Drugs

2

Description

Intervention group 2: Using one applicator of Miconazole vaginal cream every night for 7 nights.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasole Akram Hospital

Full name of responsible person

Shiva Alizadeh

Street address

Department of Midwifery; Islamic Azad University of Rasht; Pole Taleshan; Rasht; Guilan; Iran

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research; Islamic Azad University of Rasht

Full name of responsible person

Dr.Ali Mohamadi Torkashvand

Street address

Research Deputy of Islamic Azad University of Rasht;
Islamic Azad University of Rasht; Pole Taleshan;
Rasht; Guilan; Iran

City

Rasht

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for Research; Islamic Azad University of Rasht

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

Islamic Azad University of Rasht

Full name of responsible person

shiva Alizadeh

Position

MSc in Midwifery / Lecturer; Department of Midwifery

Other areas of specialty/work

Street address

Department of Midwifery; Islamic Azad University of Rasht; Pole Taleshan; Rasht; Guilan; Iran

City

Rasht

Postal code

413353516

Phone

+98 13 1666 9930

Fax

Email

gelayolalizadeh@iaurasht.ac.ir;
gelayolalizadeh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University of Rasht

Full name of responsible person

shiva Alizadeh

Position

MSc in Midwifery/ Lecturer; Department of Midwifery

Other areas of specialty/work

Street address

Department of Midwifery; Islamic Azad University of Rasht; Pole Taleshan; Rasht; Guilan; Iran

City

Rasht

Postal code

413353516

Phone

+98 13 1666 9930

Fax

Email

gelayolalizadeh@iaurasht.ac.ir;
gelayolalizadeh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University of Rasht

Full name of responsible person

Shiva Alizadeh

Position

MSc in Midwifery/ Lecturer; Department of Midwifery

Other areas of specialty/work

Street address

Department of Midwifery; Islamic Azad University of Rasht; Pole Taleshan; Rasht; Guilan; Iran

City

Rasht

Postal code

413353516

Phone

+98 13 1666 9930

Fax

Email

gelayolalizadeh@iaurasht.ac.ir;
gelayolalizadeh@yahoo.com

Web page address

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