

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the effectiveness of acetic acid gel with standard treatment on patients with vulvovaginal candidiasis: A clinical trial

Protocol summary

Study aim

Comparison of acetic acid gel with standard treatment on the treatment of patients with vulvovaginal candidiasis

Design

In this double-blinded clinical trial, 74 patients with vulvovaginal candidiasis were assigned into parallel groups using the table of random numbers based on pragmatic and community-based setting.

Settings and conduct

Vulvovaginal candidiasis patients referring to Imam Khomeini Hospital, Sari, Iran, for comparison of acetic acid gel with standard treatment were selected, using double-blinded design. The clinical care provider and data collector were blind to group assignment and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Reproductive females within the age range of 18-55 years; symptoms of irritation, itching, dysuria, and white as well as cottage cheese-like discharge from vagina; and culture-positive Candida. Exclusion criteria: Pregnancy; breastfeeding; using immunosuppressive drugs; having sexually transmitted diseases; having diabetes; having allergic to vinegar; the consumption of antibiotics, antifungal agents, or vaginal drugs in the last two weeks; and using other treatment options, such as vaginal douche.

Intervention groups

The intervention group will receive 2% acetic acid gel, intravaginal washing with 2% acetic acid, and Clotrimazole vaginal cream once a day for one week. The control group will receive intravaginal washing with 2% acetic acid and Clotrimazole vaginal cream once a day for one week.

Main outcome variables

Evaluation and comparison of the number of colonies in the culture medium in intervention and control groups after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190309042978N3**

Registration date: **2019-05-13, 1398/02/23**

Registration timing: **prospective**

Last update: **2019-05-13, 1398/02/23**

Update count: **0**

Registration date

2019-05-13, 1398/02/23

Registrant information

Name

Hamed Jafarpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1700

Email address

h.jafarpour1@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of acetic acid gel with standard treatment on patients with vulvovaginal candidiasis: A clinical trial

Public title

The effect of acetic acid gel on patients with vulvovaginal candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Reproductive females within the age range of 18-55 years Symptoms of irritation, itching, dysuria, and white as well as cottage cheese-like discharge from vagina Culture-positive Candida

Exclusion criteria:

Pregnancy Breastfeeding Using immunosuppressive drugs Having diabetes Having allergic to vinegar The consumption of antibiotics, antifungal agents, or vaginal drugs in the last two weeks Having sexually transmitted diseases Using other treatment options, such as vaginal douche

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Totally, 74 patients with vulvovaginal candidiasis referring to Imam Khomeini Hospital, Sari, Iran, were selected in this trial .The participants were assigned into intervention and control groups using the table of random numbers through a computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Vulvovaginal candidiasis patients referring to Imam Khomeini Hospital, Sari, Iran, were selected using double-blinded design. The clinical care provider and data collector were blind to group assignment and the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Vice Chancellor for Research, Mazandaran University of Medical Sciences, Farah Abad Road

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2018-06-28, 1397/04/07

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1397.1349

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**

The number of colonies

Timepoint

Before and after treatment

Method of measurement

Culture medium

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention group will receive 2% acetic acid gel, intravaginal washing with 2% acetic acid, and Clotrimazole vaginal cream once a day for one week.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive intravaginal washing with 2% acetic acid and Clotrimazole vaginal cream once a day for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Zahra Rahmani

Street address

Imam Khomeini Hospital, Amir Mazandarani Street

City

Sari

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Mazandaran

Postal code

4816633131

Phone

+98 11 3336 1700

Email

h.jafarpour@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Saeidi

Street address

Vice Chancellor for Research, Mazandaran University of Medical Sciences, Farah Abad Road

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+98 11 3335 2725

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Admission@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Zahra Rahmani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Zahra Rahmani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hamed Jafarpour

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Others

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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

Not applicable

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcome or the like can be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working at science centers and universities

Under which criteria data/document could be used

Our data will be available for scholars working at science centers and universities

From where data/document is obtainable

Hamed Jafarpour provides the data analysis to the applicants via email: h.jafarpour@mazums.ac.ir

What processes are involved for a request to access data/document

Applicants can respond to the email of the respondent and receive a response within a week.

Comments