Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Province
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
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3335 2725
Email
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
Street address
Imam Khomeini Hospital, Amir Mazandarani Street
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3336 1700
Email
h.jafarpour@mazums.ac.ir

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
Gynecology and Obstetrics
Street address
Imam Khomeini Hospital, Amir Mazandarani Street
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3336 1700
Email
h.jafarpour@mazums.ac.ir

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

Street address
Imam Khomeini Hospital, Amir Mazandarani Street

City
Sari

Province
Mazandaran

Postal code
4816633131

Phone
+98 11 3336 1700

Email
h.jafarpour@mazums.ac.ir

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