Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Study of the effect of combination therapy of Clotrimazole and Marshmallow in comparison with Clotrimazole alone on women with Candidial Vulvovaginitis

Protocol summary

Study aim

Study of Antifungal effect and reduction of fungal symptoms of combination of Clotrimazole and marshmallow cream on women with Candidial Vulvovaginitis in patient referring to AJUMS clinics

Design

In this study 100 Candidial Vulvovaginitis patients who are eligible for inclusion and exclution criteria in the study will be selected

Settings and conduct

convenience sampling will be done from all patients with Candidial Vulvovaginitis who referred to medical university gynecology clinics. These patients will be conscious about the study with provided necessary explanation. The study will be double blind and executor of plan and participants will be blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent to participate in the study Having Candidial Vulvovaginitis that approved with positive culture Age between 18_60 year old Exclusion criteria: Pregnancy Diseases affect on this disease and its treatment, such as diabetes, AIDS and STD Taking Antifungal drugs and drugs who affected on symptoms such as antihistamines and Corticosteroid Use of vaginal washing solution

Intervention groups

There are 2 groups: intervention and control, intervention group will received combination of clotrimazole 1% and marshmallow 4% vaginal cream and control group will received clotrimazole 1% vaginal cream

Main outcome variables

outcome of culture of vaginal discharge; fungal symptoms; relapse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171128037650N1**
Registration date: **2018-01-22, 1396/11/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-22, 1396/11/02**
Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

Fatemeh Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3234 5145

Email address

f_amini@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of the effect of combination therapy of Clotrimazole and Marshmallow in comparison with Clotrimazole alone on women with Candidial Vulvovaginitis

Public title
The effect of Clotrimazole and marshmallow cream on Candidial Vulvovaginitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Concious consent to participate in the study Candidial Vulvovaginitis according to positive culture result Age between 18_60

Exclusion criteria:
pregnancy Catching diseases affect on Candidial Vulvovaginitis such as diabetes, aids and sexually transmitted disease (STD) Taking of Antifungal drugs and other drugs affect on disease symptoms such as Antihistamines Use of vaginal washing solutions

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done with permuted block randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
Double blind study: plan executor, reseacher, health care personnal and participants are unaware of the drug in the two groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz university of medical science

Street address
Central office of Shiraz university of medical science, Zand Ave, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
1978_71345

Approval date
2017-11-21, 1396/08/30

Ethics committee reference number
IR.SUMS.MED.REC.139691

Health conditions studied

1

Description of health condition studied
Candidal vulvovaginitis

ICD-10 code
N77.1

ICD-10 code description
Candidal vulvovaginitis

Primary outcomes

1

Description
fungal infection symptoms

Timepoint
before the study, In the 7th day after start of the study,In the 30th day

Method of measurement
Questionnaire planned for candidal vaginitis

Secondary outcomes

1

Description
Vaginal discharge culture

Timepoint
before treatment, 7th day, 30th day after treatment

Method of measurement
culture

Intervention groups

1

Description
Intervention group: There is two groups of patients, intervention and control. intervention group will received combination of Clotrimazole 1% and marshmallow 4% vaginal cream, with applicator from first day of treatment until 7th day, at a specified time each night at bed time.

Category
Treatment - Drugs

2

Description
Control group: control group will received Clotrimazole 1% vaginal cream with applicator from first day of treatment until 7 day, at a specified time each night at bed time
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz jundishapur university of medical science clinics
Full name of responsible person
Fatemeh Amini
Street address
Ahvaz jundishapur university of medical science. Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3333 0074
Email
Amini.bahar@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr seyyed basir hashemi
Street address
Central office,Shiraz university of medical science, Zand Ave, Shiraz Sity
City
Shiraz
Province
Fars
Postal code
71345-1978
Phone
+98 71 3234 5145
Email
drjaladat@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Amini
Position
PhD Student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Shiraz university of medical science, Zand Ave.
City
Shiraz
Province
Fars
Postal code
1978-71345
Phone
+98 71 3234 5144
Email
amini.bahar@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Amini
Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Shiraz university of medical science, Zand Ave.
City
Shiraz
Province
Fars

Postal code
1978-71345
Phone
+98 71 3234 5145
Email
amini.bahar@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Amini
Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Shiraz university of medical science, Zand ave.
City
Shiraz
Province
Fars
Postal code
197871345
Phone
+98 71 3234 5145
Email
amini.bahar@gmail.com

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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Nothing
When the data will become available and for how long
Nothing
To whom data/document is available
Nothing
Under which criteria data/document could be used
Nothing
From where data/document is obtainable
Nothing
What processes are involved for a request to access data/document
Nothing
Comments