Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of two vaginal cream Artemisia kulbadica and clotrimazole in treatment of vaginal candidiasis

Protocol summary

Summary

The purpose of this study is to determine the comparison of vaginal cream Artemisia with Clotrimazole in the treatment of vaginal candidiasis. It is a random triple-blind study, which will be undertaken on 60 patients, complaining of symptoms of vulvovaginal candidiasis, after confirmation of the disease by wet smear and culture, patients will be divided into two treatment groups and will be treated with Artemisia vaginal cream (30 individuals) and Clotrimazole (30 individuals) for seven days. Patients will be examined one week ± 24 hours after the treatment through discharge culture and wet smear. In this study, recovery means the reduction of clinical signs of the disease and the negative tests of discharge culture and wet smear.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121831454N1**
Registration date: **2017-06-07, 1396/03/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-07, 1396/03/17

Registrant information

Name
Ala Sabermohammad
Name of organization / entity
School of Nursing and Midwifery, Mashhad
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-02-18, 1395/11/30

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two vaginal cream Artemisia kulbadica and clotrimazole in treatment of vaginal candidiasis

Public title

Comparison of two vaginal cream Artemisia and clotrimazole in treatment of vaginal candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: signs and symptoms of Candida vaginitis؛ positive culture and wet smear of vaginal discharge. Exclusion criteria: pregnancy؛ hypersensitivity to clotrimasol or artemisia؛ recurrent Candida vaginitis (4 or more Candida vaginitis in a year)؛ consumption of immunosuppressive drugs or systemic antibiotics؛ history of diabetes؛ using vaginal creams 2 weeks prior to the study؛ consumption of systemic anti-fungal drugs during 2 weeks prior to the study؛ presence of non-candidia vaginitis؛ consumption of oral contraceptives.

Age

From **15 years** old to **49 years** old

Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Table of random numbers

Secondary Ids

1

Registry name
In yet another center
Secondary trial Id
In yet another center
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
DoktoVice Chancellor for Research and Technology, Mashhad University of Medical Sciences, Next to the Hoveyzeh cinema, Mashhad ra Intersection, Mashhad
City
Mashhad
Postal code
Approval date
2016-10-31, 1395/08/10
Ethics committee reference number
IR.MUMS.REC.1395.385

Health conditions studied

1

Description of health condition studied
vulvovaginit candidiasis
ICD-10 code
n77.1*
ICD-10 code description
Vulvovaginal ulceration and inflammation in diseases classified elsewhere

Primary outcomes

1

Description
Discharge
Timepoint
Baseline, 1 week+_24 hours after treatment
Method of measurement
Clinical Examination, observation, and medical history

Secondary outcomes

1

Description
Pruritus
Timepoint
Baseline, 1 week+_24hours after treatment
Method of measurement
History

2

Description
Erythema symptoma
Timepoint
Baseline, 1 week _+24 hours after treatment
Method of measurement
Observation, and History

3

Description
Dysuria
Timepoint
Baseline, 1 week+_24 hours after treatment
Method of measurement
History

4

Description
Dysparonia Symptom
Timepoint
Baseline, 1 week+_ 24hours after treatment
Method of measurement
History

5

Description
Vaginal Culture
Timepoint
Baseline, 1 week+_24 hours after treatment
Method of measurement
Vaginal Culture

Intervention groups

1

Description
Intervention group: treatment with vaginal cream 0/1% Artemisia- Built in the Pharmacy School of Mashhad University of Medical Sciences-one applicator every night for a week-Intervention group
Category
Treatment - Drugs

2

Description
Control group: Treatment with vaginal cream Clotrimazole 1%- production of Aboreahan company-an applicator every night for a week-control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baze Sheakh, health Cente
Full name of responsible person
Ala sabermohammad
Street address
Street Poursina 32, Street Baze Sheakh,Mashhad
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2

Recruitment center
Name of recruitment center
Tager Abad, health center
Full name of responsible person
Ala sabermohammad
Street address
Tajer Abad health center, Street Tajer Abad, Mashhad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences - Deputy of Research and Technology
Full name of responsible person
Dr Mohsen Tafaghodi
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ViceVice Chancellor for Research and Technology, Mashhad University of Medical Sciences, Next to the Hoveyzeh cinema, MashhadIran Chancellor for Research and Technology University of Mashhad, Mashhad University of Medical Sciences, vice-chancellor for Research and Technology.
City
Mashhad
Grant name
.....
Grant code / Reference number
.....
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences - Deputy of Research and Technology
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
School of Nursing and Midwifery
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Person responsible for scientific inquiries

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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