

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 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 \pm 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

Country

Iran (Islamic Republic of)

Phone

+98 918 750 3539

Email address

saberma921@mums.ac.ir

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 clotrimazole 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-candida 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

City

Mashhad

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

City

Mashhad

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

Street address

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

Full name of responsible person

Ala sabermahammad

Position

MSc student

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

Samira Ebrahimzadeh Zagamy

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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omid kiani

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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