

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing the effect of Walnut Green Husk Vaginal Cream with Fluconazole for treatment and relapse of Candida Vaginitis

Protocol summary

Summary

The aim of this study was to comparing the effect of walnut green husk vaginal cream with Fluconazole for treatment and relapse of candida vaginitis. This randomized, double-blind study is carried out at East Ahvaz number one health center. Inclusion criteria: sign and symptoms of vulvovaginal candidiasis, married women between 18-45 years old, Patients who had a single sexual partner and they themselves were the only sexual partner of their respective spouse. Exclusion criteria: Women who had used antibiotics, immunosuppressive drugs, or any vaginal drugs 14 days before the study, pregnancy, breast feeding, diabetes and immunodeficiency side effects of the drug, 75 married women eligible for the study of vaginal discharge, itching, and burning. . . Complain and positive fungal culture, random sampling method and divided into 3 groups: 1) walnut green husk vaginal cream + Cap Placebo Fluconazole .2) Cap Fluconazole 100 mg + Placebo vaginal cream. 3) walnut green husk vaginal cream + Cap Fluconazole 100 mg, and will be examined. Physical examination, Vaginal pH and vaginal smear measured before and after interventions and compared in both the group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112819743N3**
Registration date: **2015-12-04, 1394/09/13**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-04, 1394/09/13

Registrant information

Name

Masumeh Yaralizadeh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Walnut Green Husk Vaginal Cream with Fluconazole for treatment and relapse of Candida Vaginitis

Public title

the effect of Walnut Green Husk Vaginal Cream for treatment Candida Vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: sign and symptoms of vulvovaginal candidiasis, married women between 18-45 years old, Patients who had a single sexual partner and they

themselves were the only sexual partner of their respective spouse. Exclusion criteria: Women who had used antibiotics, immunosuppressive drugs, or any vaginal drugs 14 days before the study, pregnancy, breast feeding, diabetes and immunodeficiency side effects of the drug.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Ahvaz Jundishapur University of Medical Science

Street address

Ground Floor, Department of Research and Information Technology, Ahvaz Jundishapur University of Medical Sciences, City University, Ahvaz

City

Ahvaz

Postal code

Approval date

2015-11-28, 1394/09/07

Ethics committee reference number

AJUMS.REC.1394.466

Health conditions studied

1

Description of health condition studied

Candidal vulvovaginitis

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

Complete remission

Timepoint

7 days and 14 days after treatment

Method of measurement

Evaluation of clinical symptom's remission with questionnaire

2

Description

Vaginal Culture Results

Timepoint

Before and 7 Day After intervention

Method of measurement

Esmear Vaginal

3

Description

Vaginal pH

Timepoint

Before and 7 day After intervention

Method of measurement

By pH meter strips

Secondary outcomes

empty

Intervention groups

1

Description

walnut green husk vaginal cream once applicator a day for 1 week + Cap Fluconazole 100 mg Once a days for 7 day

Category

Treatment - Drugs

2

Description

walnut green husk vaginal cream once applicator a day for 1 week + placebo Cap Once a days for 7 day

Category

Treatment - Drugs

3

Description

cap Fluconazole 100 mg Once a days for 7 day + placebo,vaginal cream,once applicator a day for 1 week.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

East's number one health center in Ahvaz

Full name of responsible person

Masumeh Yaralizadeh

Street address

7 tir park opposite, Ayatollah Behbahani
superhighway

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz JundiShapur
University of Medical Sciences

Full name of responsible person

Dr.Seyed Ahmad Hosseini

Street address

Vice Chancellor for Research, Ahvaz Jundishapur
University of Medical Sciences, opposite the central
building, Golestan Blvd.

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Ahvaz JundiShapur
University of Medical Sciences

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

Health Promotion Research Center, Ahvaz
Jundishapur University of Medical Sciences

Full name of responsible person

Salimeh Nezamivand Chegini

Position

Master of Midwifery

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Ahvaz Jundishapur
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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