Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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
Compelet remission

Timepoint
7days and 14 days after treatment

Method of measurement
Evauation of clinical symptom's remission with questionnaire

2

Description
Vaginal Culture Results

Timepoint
Before and 7 Day Aftar 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

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School of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd

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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