Comparison of Effect of Zataria Multiflora Boiss Vaginal Cream with Clotrimazol Vaginal Cream in Candida Vaginitis Treatment

Protocol summary

Summary
Candida vaginitis is the second most common infection of Vagina. Herbal extracts also are used in treatment of fungal infection. Avishan Shirazi (Zataria Multiflora Boiss) is one of herbs which have fungicidal effects. The purpose of this randomized double blind study was to determine the effects of Zataria Multiflora Boiss vaginal cream in the treatment of Candida vaginitis. The study was performed on 73 married women aged 15 to 49 years with signs and symptoms of Candida vaginitis and documented laboratory finding. The subjects were randomly assigned into two treatment groups (Avishan or Clotrimazol). One applicator of each cream was used at bed time for one week. Patients were followed 3-4 days after treatment and evaluated with tests and observation.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138807112537N1
Registration date: 2010-01-30, 1388/11/10
Registration timing: retrospective

Recruitment complete
Funding source
Researching Deputy of Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date
2003-04-21, 1382/02/01
Expected recruitment end date
2003-10-22, 1382/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Effect of Zataria Multiflora Boiss Vaginal Cream with Clotrimazol Vaginal Cream in Candida Vaginitis Treatment

Public title
Comparative Study of Zataria Multiflora Boiss Vaginal Cream and Clotrimazol in Candida Vaginitis treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: signs and symptoms of Candida vaginitis, positive direct smear of vaginal discharge
Exclusion criteria: pregnant women, low compliance, any drug hypersensitivity, recurrent Candida vaginitis (4 or more Candida vaginitis in a year), consumption of immunosuppressive drug or widespread antibiotics, history of epilepsy, diabetes, heart disease, high blood pressure, thyroid diseases, or advanced arthritis, using other vaginal creams or suppositories during the study period, consumption of systemic antifungal drugs during 4 weeks prior to the study, presence of non-candidal vaginitis, consumption of oral contraceptives.

Age
From 15 years old to 49 years old

Gender
Female

Phase
N/A

Groups that have been masked
Sample size
Target sample size: 73

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ahvaz Jundishapur University of Medical Sciences
Street address
Researching Deputy of Jondishapour Ahvaz University of Medical Sciences, Ahvaz University City, Khuzestan.
City
Ahvaz
Country
Iran (Islamic Republic of)
Postal code
empty
Ethics committee reference number
8/204566/

Health conditions studied

1
Description of health condition studied
Candida Vaginitis
ICD-10 code
B37.3
ICD-10 code description
Candidiasis of Vulva and Vagina

Primary outcomes

1
Description
Discharge
Timepoint
Baseline and 3 to 4 Days after treatment
Method of measurement
Clinical Examination, observation, and medical history

2
Description
Pruritus
Timepoint
Baseline and 3 to 4 Days after treatment
Method of measurement
History

3
Description
Edema
Timepoint
Baseline and 3 to 4 Days after treatment
Method of measurement
Clinical Examination, observation, and medical history

4
Description
Erythema symptoma
Timepoint
Baseline and 3 to 4 Days after treatment
Method of measurement
Clinical Examination, Observation, and History

5
Description
Dysuria Symptom
Timepoint
Baseline and 3-4 Days after treatment
Method of measurement
History

6
Description
Dysparonia Symptom
Timepoint
Baseline and 3 to 4 Days after the treatment
Method of measurement
History

7
Description
Culture results
Timepoint
3 to 4 Days after Treatment
Method of measurement
Wet Smear and Vaginal Culture

Secondary outcomes
empty

Intervention groups

1
Description
Herbal vaginal cream, made of Avishan Shirazi (1%) (Zataria Multiflora Boiss), one applicator every night, for 1 Week

Category
Treatment - Drugs

Description
Clotrimazole, vaginal Cream, one applicator every night, for 1 Week

Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Esmatieh health Center
Full name of responsible person
Street address
Esmatieh health Center, Health Network, Kashmar city, Khorasan Razavi
City
Kashmar
Country
Iran (Islamic Republic of)

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice-chancellor for Research, Jondishapour University of Medical Sciences
Full name of responsible person
Pourandokht Afshari
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Vice-chancellor for Research, Jondishapour University of Medical Sciences, Ahvaz University City, Khuzestan
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Country
Iran (Islamic Republic of)
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, Jondishapour 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
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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