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 status
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

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Iran (Islamic Republic of)

Postal code
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Approval date
empty

Ethics committee reference number
8/204566/п

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

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**
Esmatieh health Center

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**Sponsors / Funding sources**

**1**

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**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

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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