Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

To compare the effect of Chamelin Ahoora Daroo vaginal cream (chamomile extract)and clotrimazol vaginal cream in the treatment of Vulvovaginal Candidiasis

Protocol summary

Summary
This study is designed to evaluate the effect o f Chamomile (Ahoora Daroo) vaginal cream for the treatment of Vulvovaginal Candidiasis; and to compare this effect with the effect of clotrimazole vaginal cream. At first women who visit in the out patient clinic of Shiraz University of Medical Sciences, who are in reproductive age and have complain of Vulvovaginal itching and are without history of previous systemic disease are examined; then the possibility of Vulvovaginal Candidiasis is confirmed with, PH meter and microscopic finding. After that, a Code is given to the patients by the examiner using the random numbers table and they go to the pharmacy, and will receive their medication. Two weeks after applying the cream(10 nights) the pt will exam. The signs and symptoms of the disease will recheck (microscopic and acidity) and the result will compar by the statistical analysis. this study is triple blind.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2016051118655N2**
Registration date: **2016-10-13, 1395/07/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2016-10-13, 1395/07/22

Registrant information
Name
Tahereh Poordast
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2016-05-21, 1395/03/01
Expected recruitment end date
2018-03-20, 1396/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
To compare the effect of Chamelin Ahoora Daroo vaginal cream (chamomile extract)and clotrimazol vaginal cream in the treatment of Vulvovaginal Candidiasis

Public title
Evaluating the effect of Chamomelin vaginal cream on the management of Vulvovaginal Candidiasis.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: women in reproductive age; with diagnosis of Vulvovaginal Candidiasis exclusion criteria: menopause; systemic disease; applying vaginal cream during the previous week .
Age

From **20 years** old to **50 years** old

Gender
Female

Phase
2

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of shiraz univercity of medical sciences

Street address
Zand street Namazi square

City
Shiraz

Postal code

Approval date
2015-02-08, 1393/11/19

Ethics committee reference number
IR.SUMS.REC ct-p-9386-8186

Health conditions studied

1

Description of health condition studied
Vulvovaginal Candidiasis

ICD-10 code
B37.3+

ICD-10 code description
Candidiasis of Vulva and Vagina

Primary outcomes

1

Description
Microscopic evaluation of the hypha in Vaginal secretion

Timepoint
Befor treatment and one week (ten nights) after applying the cream

Method of measurement
Count the hypha in each field

2

Description
Check the acidity of Vagina

Timepoint
Befor and during one week after treatment

Method of measurement
PH meter

Secondary outcomes

1

Description
Signs and symptoms of Vulvovaginal Candidiasis

Timepoint
Before treatment and one week after ten nights applying the medication

Method of measurement
Evaluate the improvement and severity of signs and symptoms

Intervention groups

1

Description
case: Chamomeline Ahooradaroo Vaginal cream one applicator for ten nights

Category
Treatment - Drugs

2

Description
control group: Clotrimazol Vaginal Cream one applicator for ten nights

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Faghihi Hospital

Full name of responsible person
Dr Tahereh Poordast faculty of OB&GYN

Street address
Zand Street

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz Univercity of Medical Sciences-infertility research center

Full name of responsible person
Dr Bahia Namavar Jahromi

Street address
Zand street Namazi square Ghadir child and mother research center

City
Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz Univercity of Medical Sciences-infertility research center

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
Shiraz Univercity of Medical Sciences

Full name of responsible person
Tahereh Poordast

Position
Faculty member of OB&GYN ward

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Infertility research center ,department of obstetrics and gynecology ,school of medicine,shiraz univ

Full name of responsible person
Taherh poordast

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Board of OB&GYN

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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