Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effect of Satureja hortensis L. and clotrimazole vaginal cream in treatment of Candida vulvovaginitis

Protocol summary

Study aim
The aim of the present clinical trial study is comparison effect of Satureja hortensis L and Clotrimazole vaginal cream in treatment vulvovaginal candidiasis.

Design
In this study 84 Candidial Vulvovaginitis patients who are eligible for inclusion and exclution criteria in the study will be selected.

Settings and conduct
This randomized, double-blind study is carried out at East Ahvaz number one health center.Samples include married women aged 18 to 45 with vulvovaginal candidiasis. The sample size is 84 and the duration of the intervention is 1 weeks. Researcher and volunteer Participation in this study is completely unaware from vaginal medications , and medications tubes fill with pharmacist.Vaginal medications are all in the same package and are coded by the pharmacist. Patients eligible for the study of vaginal discharge, itching, and burning, Complain and positive fungal culture, by random sampling method will be divided into 2 groups: 1) Satureja hortensis L vaginal cream 1% , 2) clotrimazole vaginal cream 1% . The patients will use the drugs for 7 nights in one applicator (5 gram). Physical examination, Vaginal pH and vaginal smear measured before and after interventions and compared in both the group.

Participants/Inclusion and exclusion criteria
Presence of the signs and symptoms of vulvovaginal candidiasis in medical history and positive laboratory tests (smear and culture from vaginal discharge); only sexual partner; Not being pregnancy or lactation; Women that don’t use oral contraceptive pills; Not having chronic disease (diabetes, deficiency of immune system, recurrence of vulvovaginal candidiasis ,..); Not having Trichomoniasis.

Intervention groups
One group (vaginal cream Satureja hortensis L); Another group((vaginal cream Clotrimazole)

Main outcome variables
Outcome of culture of vaginal discharge; fungal symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180202038591N1**
Registration date: **2018-02-15, 1396/11/26**
Registration timing: **prospective**

Last update: **2018-02-15, 1396/11/26**
Update count: **0**

Registration date
2018-02-15, 1396/11/26

Registrant information

Name
shirin jaldani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3447 0943

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-05, 1396/12/14

Expected recruitment end date
2018-09-05, 1397/06/14

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Satureja hortensis L. and clotrimazole vaginal cream in treatment of Candida vulvovaginitis

Public title

The effect of Satureja hortensis L. cream in treatment vulvovaginal candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Signs and symptoms of vulvovaginal candidiasis Positive Gram staining smear Culture from vaginal discharge

Exclusion criteria:

Age between 18 -45 Being married Only sexual partner Signs and symptoms of vulvovaginal candidiasis Positive Gram staining smear Culture from vaginal discharge The absence of any known medical condition Lack of any allergy to coltriamzol cream and Satureja hortensis L Completion of written consent form for examination and sampling

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The specimens are randomly divided into blocks of block 4 by permutation blocks. The drugs used in this study are randomly assigned by a person outside the study according to the corresponding codes in sealed envelopes, and then assigned to any disease that is included in the study. The drugs are identical in terms of appearance, such as packaging, color. In this way, the researcher and the patient are unaware of the type of drug.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind study: Researcher and volunteer Participation in this study is completely unaware from vaginal medications , and medications tubes fill with pharmacist.Vaginal medications are all in the same package and are coded by the pharmacist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Associate Professor of Research and Information Technology, Ahvaz Jundishapur University of Medical Sciences, Academic town, Ahvaz

City

Ahwaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.AJUMS.REC.1396.878

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

Vaginal Discharge

Timepoint

Before intervention, 7 days after treatment

Method of measurement

Clinical Examination, Observation and Medical history

2

Description

Itching

Timepoint

Before intervention, 7 days after treatment

Method of measurement

History

3

Description
Vulva and Vaginal Burning
Timepoint
Before intervention, 7 days after treatment
Method of measurement
History

4

Description
Vaginal discharge culture results
Timepoint
Before intervention, 7 days after treatment
Method of measurement
Vaginal discharge culture

5

Description
Compelet remission
Timepoint
Before intervention, 7 days after treatment
Method of measurement
Evauation of clinical symptom's remission and negetive result of vaginal discharge culture

Secondary outcomes

1

Description
Dyspareunia
Timepoint
Before intervention, 7 days after treatment
Method of measurement
History

2

Description
Side Effects
Timepoint
Before intervention, 7 days after treatment
Method of measurement
Question of patient

Intervention groups

1

Description
Intervention group: Satureja hortensis L vaginal cream 1%, one applicator per day for 1 week
Category
Treatment - Drugs

2

Description
Control group: Clotrimazole vaginal cream1%, one applicator per day for 1 week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
East's number one health center in Ahwaz
Full name of responsible person
Shirin Jaldani
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7 Tir park opposite, Ayatollah Behbahani superhighway
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
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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
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available