

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the effect of vaginal cream of zizyphus spina (sider) leave with clotrimazole vaginal cream on treatment of candidiasis vulvovaginitis

Protocol summary

Study aim

The aim of this study was the effect of vaginal cream zizyphus spina leave in the treatment of candidiasis vulvovaginitis.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized

Settings and conduct

Groups after the midwife are diagnosed with vaginitis in midwifery health centers and specialized clinics of Al-Hadi Hospital in Shoushtar will be randomly and double blind (researchers and Studied groups) divided into intervention and control groups. The intervention group will use vaginal cream zizyphus spina leave and the control group will use standard treatment of vaginal candidiasis, clotrimazole 1% vaginal cream.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate vaginitis signs and symptoms in interview or observation and confirmation by laboratory study; married women between 20-45 years old; patients who had a single sexual partner and they themselves were the only sexual partner of their respective spouse; Informed consent to participate in the study. Exclusion criteria: women who had used oral or topical antifungal drugs, corticosteroids and antibiotics 2 weeks before the study; Steroid medication use; IUD use; pregnancy; breast feeding; diabetes and immunodeficiency; Abnormal uterine bleeding; menstruation and side effects of the drug.

Intervention groups

group received Vaginal cream of zizyphus spina leave

Main outcome variables

Itching; erythema; Dys Paronia;vaginal discharge; Volvo edema;Urinary irritation; improvement in vaginal discharge culture; pH value.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190805044444N1**

Registration date: **2019-09-12, 1398/06/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-12, 1398/06/21**

Update count: **0**

Registration date

2019-09-12, 1398/06/21

Registrant information

Name

Azam Honarmandpour

Name of organization / entity

Shoushtar Faculty of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3622 9544

Email address

navarbafe_n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-10, 1398/06/19

Expected recruitment end date

2020-01-09, 1398/10/19

Actual recruitment start date

2019-09-10, 1398/06/19

Actual recruitment end date

2020-01-09, 1398/10/19

Trial completion date

2020-01-09, 1398/10/19

Scientific title

Comparison of the effect of vaginal cream of zizyphus spina (sider) leave with clotrimazole vaginal cream on treatment of candidiasis vulvovaginitis

Public title

The effect of vaginal cream zizyphus spina(sider) leave in the treatment of candidacies vulvovaginitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Candidate vaginitis signs and symptoms in interview or observation and confirmation by laboratory study; married women between 20-45 years old; patients who had a single sexual partner and they themselves were the only sexual partner of their respective spouse; Informed consent to participate in the study.

Exclusion criteria:

Exclusion criteria: women who had used oral or topical antifungal drugs, corticosteroids and antibiotics 2 weeks before the study; Steroid medication use; IUD use; pregnancy; breast feeding; diabetes and immunodeficiency; Abnormal uterine bleeding; menstruation and side effects of the drug.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **96**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were randomly divided into permutation blocks with the size of block 6. The drugs used in this study were randomly assigned by the out-of-study list to the corresponding codes in the closed envelopes and then assigned to each patient who entered the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Zizyphus spina-christi green leaves vaginal cream was prepared by adding the extract to a suitable cream base (emulsion of water in oil) at concentrations of 5% . In the pharmacy, 1% of clotrimazole vaginal cream was prepared using the same base. All final products had the same appearance and an approved color was used to maintain uniformity. Microbiological and physicochemical tests (uniformity, physical stability, distribution, and acidity) were performed on the prepared formulations. Samples will be randomly assigned to A and B

medication. Both Zizyphus spina-christi leaves vaginal cream and clotrimazole 1% can be used with applicators and are named A and B because the researcher and research units are unaware of them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shoushtar faculty of medical sciences

Street address

Shoushtar Faculty of Medical Sciences, Alhade hospital, Rajae BLV, Shoushtar

City

shoushtar

Province

Khuzestan

Postal code

64516-84534

Approval date

2019-07-10, 1398/04/19

Ethics committee reference number

IR.SHOUSHTAR.REC.1398.008

Health conditions studied

1

Description of health condition studied

candidacies 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

Evaluation of clinical symptom's remission with questionnaire

2

Description

Vaginal Culture Results

Timepoint

Before and 7 Day After 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

Intervention group:vaginal cream of zizyphus spina (sider) leave once applicator a day for 1 week

Category

Treatment - Drugs

2

Description

Control group: Clotrimazole vaginal cream once applicator a day for 1 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers and the Specialized Clinic of Al-Hadi Hospital in Shuoshtar

Full name of responsible person

Azam Honarmandpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shoushtar Faculty of Medical Sciences

Full name of responsible person

Deputy Research and technology Shoushtar Faculty of Medical Sciences

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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

Shoushtar Faculty 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

Shoushtar Faculty of Medical Sciences

Full name of responsible person

Azam Honarmandpour

Position

MSC of Midwifery, Shoushtar Faculty of Medical Sciences, Shoushtar, Iran.

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The part of the data includes information about the main consequences or the like it is possible to share

When the data will become available and for how long

Start the access period 12 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions will be available

Under which criteria data/document could be used

The data was used to check fungal infections in other parts of the body.

From where data/document is obtainable

By receiving the email of the responsible author at honarmandpour.a@gmail.com

What processes are involved for a request to access data/document

After requesting data by email, the data will be sent within 1-2 weeks

Comments