

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessing the effect of vaginal Shallomine containing pure fraction of shallot extract and clotrimazole in treatment of candidal vaginitis

Protocol summary

Study aim

Evaluation of the effect of Shalomine in treatment of candidal vaginitis

Design

Clinical trial with control group, with parallel groups, randomized, phase 2 on 30 patients. Random number table is used for randomization.

Settings and conduct

The samples include women with candidal vaginitis according to their clinical symptoms. After completing the informed consent form by the volunteer patients, the doctor take the vaginal sample using a sterile swab. The swabs transfer to the laboratory with dextrose broth and culture on specific medium of Chrom Candida agar. After positive candida culture and diagnosis of candidal vaginitis, patients are randomly allocated into two groups of 15 persons and are given shalomin (2 cc of the drug deep into the vagina with a sterile syringe twice a day for 5 days). The second group are given the clotrimazole daily for a week. At the end of the treatment period, clinical vaginal examinations and culture are performed and the two groups are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged between 18 and 50 years: Married; Have a spouse ; Consent to participate in the study ; Lack of sensitivity to herbal drugs; Lack of sensitivity to clotrimazole; Being Literate. Exclusion criteria: Taking antibiotics and corticosteroids in the last two weeks according to the participant's statements; Existence of any wound or mass in the cervix based on observation with speculum ; using other herbal medicines; Have abnormal uterine bleeding

Intervention groups

Patients with candidal vaginitis taking shalomin: patients with candidal vaginitis taking clotrimazole

Main outcome variables

Vaginitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190728044356N1**

Registration date: **2020-12-07, 1399/09/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-07, 1399/09/17**

Update count: **0**

Registration date

2020-12-07, 1399/09/17

Registrant information

Name

Sousan Akrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 7443

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of vaginal Shallomine containing pure fraction of shallot extract and clotrimazole in treatment of candidal vaginitis

Public title

Clinical trial on comparing the effect of vaginal Shallomine containing the pure fraction of shallot extract and clotrimazole in treatment of candidal vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

aged between 18 and 50 years Be married Have 1 spouse Have consent to participate in the study Not allergic to herbal medicines Not allergic to clotrimazole Be literate

Exclusion criteria:

They have been taken antibiotics and corticosteroids for the past two weeks, according to the participant Have any sores or lumps in the cervix based on observation with speculum Present use of other herbal medicines Have abnormal uterine bleeding

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

This randomized controlled trial was designed in two parallel groups using a random block table of 8 blocks of 4. Random sequences were generated using WinPEPI (version 11.43) and the ratio assignment was 1: 1. For example, block 1: 1: A 2: A 3: B 4: B The codes are the letters A and B, the letter A being the test drug, and the letter B the control. The drugs were numbered sequentially, but the patient and physician did not know the codes. Codes are assigned to patients in the order of patient entry. After the results are announced, the numbers are matched by the epidemiologist with the codes and it is determined which number is related to the test and which number is related to the control.

Blinding (investigator's opinion)

Not 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 in Research of Ahvaz Jundishapur University

Street address

University City, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences and Health Services, Ground Floor

City

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Province

Khouzestan

Postal code

15794- 61357

Approval date

2020-10-26, 1399/08/05

Ethics committee reference number

IR.AJUMS.REC.1399.564

Health conditions studied

1

Description of health condition studied

Candidiasis

ICD-10 code

B37

ICD-10 code description

Candidiasis

2

Description of health condition studied

Candidiasis of vulva and vagin

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

Percentage of people with candidal vaginitis

Timepoint

Examination of Candida in the patient's vaginal discharge before the intervention and one week after taking the drug

Method of measurement

culture and Laboratory diagnosis of Candida

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Shalomine, 2 cc, deep vaginal inoculation with sterile syringe, twice daily for 5 days

Category

Treatment - Drugs

2

Description

Intervention group: Clotrimazole, daily for one week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Obstetrics and Gynecology Clinic

Full name of responsible person

Raziyeh Mohammad Jafari

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Naderi Street, between Ferdowsi and Hafez

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mansour Amin

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Ahvaz - Golestan Blvd., Shahr-e Daneshgahi, Esfand St., Ahvaz Jundishapur University 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

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

Ahvaz University of Medical Sciences

Full name of responsible person

Sousan Akrami

Position

student

Latest degree

Master

Other areas of specialty/work

Microbiology

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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

No - There is not 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

Not applicable

Data Dictionary

Not applicable