

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Email address

sahm647094@gmail.com

##### 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

Ahvaz

##### Province

Khuzestan

##### 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

#### Street address

Naderi Street, between Ferdowsi and Hafez

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mohamadjafari-r@ajums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Ahvaz University of Medical Sciences

#### Full name of responsible person

Mansour Amin

#### Street address

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

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#### Email

sahm647094@gmail.com

#### 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

#### Street address

Department of Microbiology, Ahvaz Jundishapur University of Medical Sciences, Esfand St., Golestan Blvd.

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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#### Position

professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Microbiology

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**Person responsible for updating data**

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**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

**Street address**

Department of Medical Microbiology, Ahvaz  
Jundishapur University of Medical Sciences, Esfand  
St., Golestan Blvd.

**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