

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Bon Sorkh vaginal gel with vaginal cream of clotrimazole on treatment of vulvovaginal candidiasis

Protocol summary

Study aim

Comparison of vaginal Bon Sorkh with clotrimazole on treatment of vulvovaginal candidiasis.

Design

Sham controlled clinical trial with a parallel group design, Randomised

Settings and conduct

All married women at reproductive age referring to women's clinics of Ahvaz Razi Hospital who complained for vaginal infections were considered as the population under study. The sample size in this study was determined 50 people in each group. The first group which included 50 patients nightly used 1% clotrimazole vaginal cream (Raha Pharmaceutical Co.) with an applicator for 7 days. The second group which included 50 patients nightly applied - 3% Bon sorkh vaginal cream with an applicator for 7 days.

Participants/Inclusion and exclusion criteria

They were not at pregnancy or breast-feeding stage and did not consume alcohol. They had not used antibiotics, immunosuppressive drugs, or vaginal drugs 14 days before the study. They had not previously suffered from known medical diseases such as diabetes, immune system attenuating diseases (such as AIDS) or auto-immune diseases, coagulation disorders, and epilepsy.

Intervention groups

The first group which included 50 patients nightly used 1% clotrimazole vaginal cream (Raha Pharmaceutical Co.) with an applicator for 7 days. The second group which included 50 patients nightly applied - 3% Bon sorkh vaginal cream with an applicator for 7 days.

Main outcome variables

Vaginal discharge, Pruritus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161031030595N2**

Registration date: **2018-03-17, 1396/12/26**

Registration timing: **prospective**

Last update: **2018-03-17, 1396/12/26**

Update count: **0**

Registration date

2018-03-17, 1396/12/26

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 938 300 1511

Email address

shirani.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-14, 1397/01/25

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Bon Sorkh vaginal gel with vaginal cream of clotrimazole on treatment of vulvovaginal candidiasis

Public title

Comparison of vaginal Bon Sorkh with clotrimazole on treatment of vulvovaginal candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

They were not at pregnancy. They had not used antibiotics, immunosuppressive drugs, or vaginal drugs 14 days before the study

Exclusion criteria:

They had not previously suffered from known medical diseases such as diabetes, immune system attenuating diseases (such as AIDS) or auto-immune diseases, coagulation disorders, and epilepsy.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

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

Esfand, Golestan

City

Ahvaz

Province

Khouzestan

Postal code

5794-61357

Approval date

2016-09-27, 1395/07/06

Ethics committee reference number

IR.AJUMS.REC.1395.374

Health conditions studied

1

Description of health condition studied

Vulvovaginal Candidiasis

ICD-10 code

N77.1

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

Vaginal discharge

Timepoint

Initially, four and eight days after treatment

Method of measurement

Self-administered questionnaire

Secondary outcomes

1

Description

Pruritus

Timepoint

Initially, four and eight days after treatment

Method of measurement

Self-administered questionnaire

Intervention groups

1

Description

In the control group, clotrimazole vaginal cream

Category

Treatment - Drugs

2

Description

In the intervention group, vaginal gel bonsorkh

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Razi Hospital

Full name of responsible person

Heibatullah Kalantari

Street address

Amanieh St, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Badavi Mohhamad
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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
School of Pharmacy, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Heibatullah kalantari
Position
Professor
Latest degree
Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Position

student

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Ph.D.

Other areas of specialty/work

Toxicology

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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

Undecided - It is not yet known if there will be 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