

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison the effect of Lawsonia inermis (henna) vaginal cream with clotrimazole vaginal cream on treatment and relapse of candida vaginitis

Protocol summary

Summary

The aim of this study was to comparing the effect of Lawsonia inermis (henna) vaginal cream with clotrimazole vaginal cream on treatment and relapse of candida vaginitis. This randomized, double-blind study is carried out at East Ahvaz number one health center. Inclusion criteria: sign and symptoms of vulvovaginal candidiasis, married women between 18-45 years old, patients who had a single sexual partner and they themselves were the only sexual partner of their respective spouse. Exclusion criteria: women who had used antibiotics, immunosuppressive drugs, or any vaginal drugs 14 days before the study; pregnancy; breast feeding; diabetes and immunodeficiency side effects of the drug. 75 married women eligible for the study of vaginal discharge, itching, and burning. . . complain and positive fungal culture, by random sampling method divided into 2 groups: 1) Lawsonia inermis (henna) vaginal cream and 2) clotrimazole vaginal cream. Physical examination, vaginal pH and vaginal smear measured before and after interventions will be compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022119743N4**

Registration date: **2016-03-06, 1394/12/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-06, 1394/12/16

Registrant information

Name

Masumeh Yaralizadeh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 7543

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz JundiShapur University of Medical Sciences

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2016-12-31, 1395/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Lawsonia inermis (henna) vaginal cream with clotrimazole vaginal cream on treatment and relapse of candida vaginitis

Public title

The effect of Lawsonia inermis (henna) vaginal cream on treatment of candida vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: sign and symptoms of vulvovaginal candidiasis; married women between 18-45 years old; patients who had a single sexual partner and they themselves were the only sexual partner of their

respective spouse. Exclusion criteria: women who had used antibiotics, immunosuppressive drugs, or any vaginal drugs 14 days before the study; pregnancy; breast feeding; diabetes and immunodeficiency side effects of the drug.

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Ahvaz Jundishapur University of Medical Science

Street address

Ground Floor, Department of Research and Information Technology University of Medical Sciences, City University, Ahvaz

City

Ahvaz

Postal code

Approval date

2016-02-09, 1394/11/20

Ethics committee reference number

AJUMS.REC.1394.616

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

Complete remission

Timepoint

Seven and 14 days after treatment

Method of measurement

Evaluation of clinical symptom's remission with questionnaire

Secondary outcomes

1

Description

Vaginal pH

Timepoint

Before intervention and 7 days after intervention

Method of measurement

By pH meter strips

2

Description

Vaginal culture results

Timepoint

Before intervention and 7 days after intervention

Method of measurement

Vaginal smear

Intervention groups

1

Description

Clotrimazole vaginal cream once applicator a day for 1 week

Category

Treatment - Drugs

2

Description

Lawsonia inermis (henna) vaginal cream once applicator a day for 1 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

East's number one health center in Ahvaz

Full name of responsible person

Masumeh Yaralizadeh

Street address

7 tir park opposite, Ayatollah Behbahani superhighway

City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz JundiShapur University of Medical Sciences

Full name of responsible person

Dr. Nader Saki

Street address

Opposite the central building, Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Ahvaz JundiShapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Health Promotion Research Center, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Salimeh Nezamivand Chegini

Position

Master of Midwifery

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty