Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

yaralizadeh.m@ajums.ac.ir

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
Compelet remission

Timepoint
Seven and 14 days after treatment

Method of measurement
Evauation 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
Street address
School of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
City
Ahvaz
Postal code
Phone
+98 61 3336 7543
Fax
Email
yaralizadeh.m@ajums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Health Promotion Research Center, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Masumeh Yaralizadeh
Position
Master of midwifery
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
City
Ahvaz
Postal code
Phone
+98 61 3336 7543
Fax
Email
Yaralizadeh.m@ajums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Health Promotion Research Center, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Yaralizadeh Masumeh
Position
Master of Midwifery
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
City
Ahvaz
Postal code
00986133367543
Phone
+98 61 3336 7543
Fax
Email
Yaralizadeh.m@ajums.ac.ir
Web page address

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