Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison effect of Alum and Clotrimazole vaginal cream in treatment vulvovaginal candidiasis.

Protocol summary

Study aim
The comparison of Alum vaginal solution and Clotrimazole vaginal cream in treatment vulvovaginal candidiasis

Design
A randomized, controlled clinical trial with a parallel group design of 72 patients,

Settings and conduct
This study are performed in selected care Center affiliated to Ahvaz JundiShapur University of Medical Sciences

Participants/Inclusion and exclusion criteria
Inclusion criteria: Being between 18 and 45 years old ؛ Willingness to participate in the study ؛ Being married ،Existence of clinical signs indicating candidiasis vaginitis ؛ Positive wet smear for candida Exclusion criteria: Pregnancy ؛ Breastfeeding ؛ Abnormal uterine bleeding ؛ Body mass index equal to or greater than 30 ؛ History of known chronic diseases: diabetes, weakened immune system, epilepsy, hypertension, etc. ؛ History of recurrent candidiasis vulvovaginitis (4 or more than 4 times a year) ؛ Existence of other vaginal infections with candidiasis ؛ Taking oral contraceptive pills ؛ Taking corticosteroids and antibiotics in the last 2 weeks ؛ Taking systemic antifungal drugs in the last 4 weeks ؛ Taking a cream, suppository or vaginal douche in the last 48 hours ؛ History of allergy to clotrimazole

Intervention groups
1-Alum vaginal solution 2- Clotrimazole vaginal cream

Main outcome variables
1)Symptoms of vaginal candidiasis (including: pruritus, vaginal soreness, dyspareunia, external dysuria, and abnormal vaginal discharge) and; 2) Signs of vaginal candiasis (Including; vaginal erythema, excoriations, thick white adherent discharge, and swelling). 3) the side defects of the medications after treatment

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200916048736N1**
Registration date: **2020-11-14, 1399/08/24**
Registration timing: **prospective**

Last update: **2020-11-14, 1399/08/24**
Update count: **0**

Registration date
2020-11-14, 1399/08/24

Registrant information
Name
Sorour Soltani hoveizeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3332 5524
Email address
soltani_so@ajums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-15, 1399/08/25
Expected recruitment end date
2021-01-09, 1399/10/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The comparison effect of Alum and Clotrimazole vaginal cream in treatment vulvovaginal candidiasis.

Public title
The effect of Alum vaginal solution in vaginal candidiasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being between 18 and 45 years old Willingness to participate in the study Being married Existence of clinical signs indicating candidiasis vaginitis Positive wet smear for candida
Exclusion criteria:
Pregnancy Breastfeeding Abnormal uterine bleeding Body mass index equal to or greater than 30 History of known chronic diseases: diabetes, weakened immune system, epilepsy, hypertension, etc. History of recurrent candidiasis vulvovaginitis (4 or more than 4 times a year) Existence of other vaginal infections with candidiasis Taking oral contraceptive pills Taking corticosteroids and antibiotics in the last 2 weeks Taking systemic antifungal drugs in the last 4 weeks Taking a cream, suppository or vaginal douche in the last 48 hours History of allergy to clotrimazole
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants by method Random blocks are divided into two groups of intervention and control using 6 blocks. The blocks will be provided by Excel software with Rand's formula and the six blocks will be placed in closed envelopes respectively prepared by EXCEL , and the patients will be placed in one of the blocks by opening it.
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 of Ahvaz Jundishapur University of Medical Sciences
Street address
Ground Floor, Department of Research and Information Technology Jundishapur University of Medical Sciences, City University, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2020-11-01, 1399/08/11
Ethics committee reference number
IR.AJUMS.REC.1399.628

Health conditions studied

1

Description of health condition studied
Vaginal Candidiasis
ICD-10 code
N77.1
ICD-10 code description
Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere

Primary outcomes

1

Description
Symptoms of vaginal candidiasis (including: pruritus, vaginal soreness, dyspareunia, external dysuria, and abnormal vaginal discharge)
Timepoint
Before intervention and 7 days after intervention
Method of measurement
Completing the checklist to assess the symptoms vaginal candidiasis and then comparing the frequency of the Symptoms of vaginal candidiasis within and between two groups of treatment

2

Description
Signs of vaginal candiasis (Including; vaginal erythema, excoriations, thick white adherent discharge)
Timepoint
Before intervention and 7 days after intervention
Method of measurement
Completing the checklist to assess the Signs of Vaginal Candidiasis following vaginal examination and observation. Then comparing the frequency of the signs of vaginal candidiasis within and between two groups of treatment

3

Description
the possible side defects of the medications after treatment
Timepoint
During the intervention and 7 days after the intervention
Method of measurement
Completing the checklist to assess the possible side effects of the medications and then comparing the frequency of the side effects within and between two groups of treatment

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Clotrimazole vaginal cream1%,Pars Daroo Company , one applicator per day for 1 week.
Category
Treatment - Drugs

2

Description
Intervention group: White alum powder is made from perfumery and with a concentration of 13.33% (4 g of alum in 30 cc of distilled water) after autoclaving the solution is packed in 250 cc containers. The subjects will use 10 cc of the solution three times a day for a 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
Sorour Soltani
Street address
7 tir park opposite, Ayatollah Behbahani superhighway
City
Ahvaz
Province
Khouzestan
Postal code
6173663369
Phone
+98 61 3222 7800
Email
sororsoltani@gmail.com
Web page address

2

Recruitment center
Name of recruitment center
East's number six health center in Ahvaz
Full name of responsible person
Sorour Soltani
Street address
Opposite Vahdat Elementary School, Fourth Crossroads, 3rd Street, Hasirabad Alley
City
ahvaz
Province
Khouzestan
Postal code
6173663369
Phone
+98 61 3224 1269
Email
sororsoltani@gmail.com

3

Recruitment center
Name of recruitment center
Mahdis Alley-East's number 15 health center in Ahvaz
Full name of responsible person
Sorour Soltani
Street address
At the beginning of Nishkar Street 2، Mahdis Alley
City
Ahvaz
Province
Khouzestan
Postal code
6185695411
Phone
+98 61 3293 1138
Email
sororsoltani@gmail.com

4

Recruitment center
Name of recruitment center
East's number 8 health center in Ahvaz
Full name of responsible person
Sorour Soltani
Street address
Next to Alnabi Mosque, Danesh Street, Bahonar Alley
City
Ahvaz
Province
Khouzestan
Postal code
6178663141
Phone
+98 61 3228 4799
Email
sororsoltani@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mehdi Ahmadi Moghadam
Street address
Researching Deputy of Jondishapour Ahvaz University of Medical Sciences, Ahvaz University City, Khouzestan
City
Ahvaz
Province
Khouzestan
Postal code
6135715749
Phone
+98 61 3336 2414
Email
iitc@ajums.ac.ir
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
Dr Mina Iravani
Position
A Member Academic-Associated Profesor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing and Midwifery, Jondishapour University of Medical Sciences, Ahvaz University City
City
Ahvaz
Province
Khouzestan
Postal code
6135715749
Phone
+98 938 024 0406
Email
minairavani2004@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mina Iravani
Position
A Member Academic-Associated Profesor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing and Midwifery, Jondishapour University of Medical Sciences, Ahvaz University City
City
Ahvaz
Province
Khouzestan
Postal code
6135715749
Phone
+98 938 024 0406
Email
minairavani2004@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mina Iravani
Position
A Member Academic-Associated Profesor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing and Midwifery, Jondishapour University of Medical Sciences, Ahvaz University City
City
Ahvaz
Province
Khouzestan
Postal code
6135715749
Phone
+98 938 024 0406
Email
minairavani2004@yahoo.com

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