Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparative study on the effect of herbal vaginal suppository containing oat gall extract and Clogin vaginal suppository in treatment of vaginal candidiasis

Protocol summary

Study aim
Evaluation of effectiveness of oat gall suppository in comparison with clogin suppository in treatment of vulvovaginal candidiasis

Design
This is a Randomized parallel group, clinical trial, double blinded.

Settings and conduct
This study are performed in a selected care Center affiliated to Khorramabad University.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Married women aged between 18 to 44 years Old non- pregnant; non-breastfeeding, non-menopaused; No vaginal bleeding; Not taking any vaginal cream or suppository medications during the previous 48 hours; not taking any antibiotics or antifungal medications for vaginitis during the previous 2 weeks; not taking any corticostroids during the previous 2 weeks; Patient with vaginal candidiasis; No history of chronic diseases Exclusion criteria: Existance of other vaginal infections; Pregnancy during the study period; Participation in another trial; Occurrence of side effects

Intervention groups
1-Oat gall suppository 2-Clogin Suppository

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: **IRCT20190306042943N2**
Registration date: **2019-05-02, 1398/02/12**
Registration timing: **prospective**

Last update: **2019-05-02, 1398/02/12**
Update count: **0**

Registration date
2019-05-02, 1398/02/12

Registrant information

Name
Mohaddese Mahboubi

Name of organization / entity
Tabibdaru

Country
Iran (Islamic Republic of)

Phone
+98 31 5554 1000

Email address
mahboubi1357@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2020-08-22, 1399/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study on the effect of herbal vaginal suppository containing oat gall extract and Clogin vaginal

suppository in treatment of vaginal candidiasis

Public title
Study on the effect of oat galls in vaginal candidiasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Married women aged between 18 to 44 years Old non-pregnant, non-breastfeeding, non- menopaused No vaginal bleeding Not taking any vaginal cream or suppository medications during the previous 48 hours not taking any antibiotics or antifungal medications for vaginitis during the previous 2 weeks not taking any corticostroids during the previous 2 weeks Patient with vaginal candidiasis No history of chronic diseases
Exclusion criteria:
Existance of other vaginal infections Pregnancy during the study period Participation in another trial Occurrence of side effects
Age
From **18 years** old to **44 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **55**
Randomization (investigator's opinion)
Randomized
Randomization description
This is a single-center randomized, double-blind clinical trial study. In the present study, married women aged between 18 to 44 years old, with symptoms of vaginal candidiasis are recruited for primary evaluation. After diagnosis of vaginal candidiasis, the participants will receive Clogin (1% Clotrimazole) vaginal suppository or oat gall vaginal suppository which are coded as "A" and "B" by the pharmacologist, and researchers and the participants are blinded about the composition of medications. Excel Randomization scale will be used to devote participants for treating by medications coded as "A" or "B" . After data analysis, and opening the codes, the participants who were treated by Clogin (1% Clotrimazole) vaginal suppository would be considered as the control group and the the participants who were treated by oat gall vaginal suppository would be considered as the intervention group (55 person in each group).
Blinding (investigator's opinion)
Double blinded
Blinding description
Clogin and Oat gall Suppository are made similarly and then coded as "A" and "B" by the pharmacologist. So, the clinician, researchers and the participants are blinded about the composition of medications (Double blind) until the opening the codes after data analysis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Ethics Committee on Biological Research
Street address
Shahid Beheshti Medical university School of Nursing & Midwifery, Vali Asr Ave., Niayesh Cross Road, Niayesh Complex, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2018-12-03, 1397/09/12
Ethics committee reference number
IR.SBMU.Pharmacy.REC.1397.184

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
2) 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
Before intervention and 7 days after 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
The control group: The 55 subjects in this group will be treated by Clogine suppository containing 1% clotrimazole, one suppository for 7 nights. The participants will complete the demographic and reproductive questionnaire. Then two checklists; including 1) checklist of symptoms of vaginal candidiasis and 2) Checklist of signs of vaginal candiasis; will be completed twice, first: with initiating of treatment and second: 7 days following treatment completion. Also, they will complete the form for assessing the side efects of the medications after treatment.
Category
Treatment - Drugs

2

Description
The intervention group: The 55 subjects in this group will be treated by vaginal herbal suppository containing oat gall extract one suppository for 7 nights. The participants will complete the demographic and reproductive questionnaire. Then two checklists; including 1) checklist of symptoms of vaginal candidiasis and 2) Checklist of signs of vaginal candiasis; will be completed twice, first: with initiating of treatment and second: 7 days following treatment completion. Also, they will complete the form for assessing the side efects of the medications after treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Care Clinic in Khoramabad
Full name of responsible person
Dr. Masoumeh Simbar
Street address
Midwifery and Reproductive Health Research Center, Shahid Beheshti University of Medical Sciences
Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19839-63113
Phone
+98 21 8865 5376
Email
msimbar@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabib Daru Dez.
Full name of responsible person
Dr. M. Mahboubi
Street address
No. 3, Homa Building, Bayan 2, Motaheri Street
City
Kashan
Province
Isfehan
Postal code
87151155815
Phone
+98 31 5554 1000
Email
mahboubi1357@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabib Daru Dez.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Tabibdaru
Full name of responsible person
Mohaddese Mahboubi
Position
Research and Development Manager
Latest degree
Ph.D.
Other areas of specialty/work
Microbiology
Street address
Homa Building, Motahari Street, Kashan, Iran
City
Kashan
Province
Isfehan
Postal code
8715115815
Phone
+98 31 5554 1000
Fax
+98 31 5554 1000 ext. 105
Email
mahboubi1357@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Masoumeh Simbar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Midwifery and Reproductive Health Research Center, Shahid Beheshti University of Medical Sciences, Cross of Vali-Asr and Hashemi Rafsanjani Highway, Opposite to Rajaee Heart Hospital, Tehran, Iran
City
tehran
Province
Tehran
Postal code
1996835119
Phone
+98 21 8865 5376
Fax
+98 21 8865 5376
Email
msimbar@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabibdaru
Full name of responsible person
Mohaddese Mahboubi
Position
Research and Development Manager
Latest degree
Ph.D.
Other areas of specialty/work
Microbiology
Street address
Homa Building, Motahari Street, Kashan, Iran
City
Kashan
Province
Isfehan
Postal code
8715115815
Phone
+98 31 5554 1000
Fax
+98 31 5554 1000 ext. 105
Email
mahboubi1357@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no furthur information
Study Protocol
No - There is not 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