

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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-menopausal; 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 corticosteroids 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-menopausal 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 corticosteroids during the previous 2 weeks Patient with vaginal candidiasis No history of chronic diseases

Exclusion criteria:

Existence 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 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 candidiasis (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 candidiasis; 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 effects 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 candidiasis; 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 effects 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

Isfahan

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

Isfahan

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

Isfahan

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 further 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