# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 May 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

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**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
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**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**
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## Sponsors / Funding sources

**1**

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**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

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## 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