

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### The effect of vaginal boswellia gel on vaginal candidiasis in firoozgar hospital with smear and culture

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of frankincense vaginal gel with overnight use for one week in the treatment of clinical and laboratory symptoms in culture and smear of candidal vaginal infection in patients

##### Design

Three-way blind clinical trial, with control group, randomized, phase 3 on two groups of 90 patients. A table of random numbers and 4 blocks will use for randomization.

##### Settings and conduct

Patients treated with symptoms and diagnosis of candidal vaginitis referred to the clinic will treat with frankincense gel, frankincense gel for one week at night.

##### Participants/Inclusion and exclusion criteria

Criteria for admission to the study: married women aged 20 to 55 who referred to hospitalization centers despite symptoms of vaginal candidiasis, including burning, itching, pain and dys paronis, Criteria for non-entry: antibiotic use in the last two weeks, pregnancy, lactation, mental retardation, addiction, systemic corticosteroid or OCP use, diabetes, anatomical problems of the vulva and vagina, concomitant genital infection, vaginal bleeding of origin Unknown Criteria for withdrawal : no improvement in clinical symptoms after 72 hours from the start of the drug, pregnancy, patient dissatisfaction with continuing treatment, drug side effects, failure to take 3 doses (3 nights)

##### Intervention groups

An applicator of the drug will administer vaginally for seven nights. The form of drug side effects is given to the patient and the necessary explanations will give. If the test results are negative, the patient will be excluded from the study. After 48 hours from the end of the medication (9 days after the first visit), a face-to-face visit and re-filling of the questionnaires is performed. During the study period, appropriate action will be taken if any of the exit criteria are met.

##### Main outcome variables

pain, Burning, Itching, Dispareunia, vaginal discharge

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200701047977N1**

Registration date: **2021-07-04, 1400/04/13**

Registration timing: **prospective**

Last update: **2021-07-04, 1400/04/13**

Update count: **0**

##### Registration date

2021-07-04, 1400/04/13

##### Registrant information

##### Name

Fazele Heydarian Moghadam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2277 6707

##### Email address

dr.fheydarian@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-21, 1400/05/30

##### Expected recruitment end date

2021-11-21, 1400/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of vaginal boswellia gel on vaginal candidiasis in firoozgar hospital with smear and culture

### Public title

The effect of vaginal boswellia gel on vaginal candidiasis

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

female 20 - 55 years old married itching, burning, pain, dyspareunia diagnose of vaginal candidiasis by physician do not use of antibiotic and corticosteroide in 2weeks ago

#### Exclusion criteria:

use of antibiotic in 2 weeks ago pregnancy breastfeeding backward addiction use of systemic corticosteroid or OCP diabetes anatomic problems in vulve and vagina other sexual infections abnormal vaginal bleeding

### Age

From **20 years** old to **55 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **180**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this study, randomization will performe using a table of random numbers with 4 blocks. It is an individual randomization unit.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

In this study, the patient, the researcher, the sampler, the evaluator, the data collector, and the data monitoring committee will all seat.

### Placebo

Used

### Assignment

Factorial

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical Committee of Shahid Beheshti University of Medical Sciences

##### Street address

Traditional Medicine University, Shams Alley, Valiasr Street

##### City

Tehran

##### Province

Tehran

##### Postal code

1995865754

##### Approval date

2021-01-31, 1399/11/12

##### Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1008

## Health conditions studied

### 1

#### Description of health condition studied

vaginit candidiasis

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Comparison of symptoms of pain, burning, itching and vaginal discharge in patients with candidal vaginal infection

#### Timepoint

2 days after treatment

#### Method of measurement

Filling in the clinical symptoms questionnaire of the Iranian Dermatological Association

### 2

#### Description

Comparison of symptoms of burning in patients with candidal vaginal infection

#### Timepoint

2 days after treatment

#### Method of measurement

Filling in the clinical symptoms questionnaire of the Iranian Dermatological Association

### 3

#### Description

Comparison of symptoms of itching in patients with candidal vaginal infection

#### Timepoint

2 days after treatment

#### Method of measurement

Filling in the clinical symptoms questionnaire of the

#### 4

##### **Description**

Comparison of symptoms of vaginal discharge in patients with candidal vaginal infection

##### **Timepoint**

2 days after treatment

##### **Method of measurement**

Filling in the clinical symptoms questionnaire of the Iranian Dermatological Association

#### 5

##### **Description**

Comparison of symptoms of dyspareunia in patients with candidal vaginal infection

##### **Timepoint**

2 days after treatment

##### **Method of measurement**

Filling in the clinical symptoms questionnaire of the Iranian Dermatological Association

## **Secondary outcomes**

empty

## **Intervention groups**

#### 1

##### **Description**

Intervention group: Prescribing frankincense vaginal gel containing 2% frankincense. First, glyprol propylene extract: water (20-80) is prepared by fumigation by frankincense. The prepared extract is dissolved in 1% carbomer 940 solution. By alkalizing the resulting solution, the gel is formed. Vaginally take an applicator for up to 7 nights

##### **Category**

Treatment - Drugs

## **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Firoozgar Hospital, Tehran

###### **Full name of responsible person**

Mojgan Tansaz

###### **Street address**

Shams Alley, Valiasr Street

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1995865754

###### **Phone**

+98 21 2254 0233

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

###### **Full name of responsible person**

Somaye Esmaeili

###### **Street address**

Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Yemen Street, Shahi

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1995865754

###### **Phone**

+98 21 2254 0233

###### **Email**

dr.fheydarian@yahoo.com

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

###### **Full name of responsible person**

Mojgan Tansaz

###### **Position**

professor

###### **Latest degree**

Ph.D.

###### **Other areas of specialty/work**

Traditional Medicine

###### **Street address**

Shams Alley, Valiasr Street

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## Person responsible for scientific inquiries

### Contact

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Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
professor  
**Latest degree**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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**Position**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data can be shared

### When the data will become available and for how long

Available 6 months after printing

### To whom data/document is available

For researchers in academic institutions

### Under which criteria data/document could be used

For researchers in academic institutions

### From where data/document is obtainable

Contact to responsible author

### What processes are involved for a request to access data/document

After coordination with the responsible author, the information will be received by the applicant within two weeks

### Comments