

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@sbfmu.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

City

Tehran

Province

Tehran
Postal code
1995865754
Phone
+98 21 2254 0233
Email
dr.fheydarian@yahoo.com

Person responsible for scientific 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
City
Tehran
Province
Tehran
Postal code
1995865754
Phone
+98 21 2254 0233
Email
dr.fheydarian@yahoo.com

Person responsible for updating data

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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dr.fheydarian@yahoo.com

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