

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### A vaginal dosage form preparation of Gall and Myrtle and study of their effects in bacterial vaginitis via double blind randomized clinical trial with placebo control

#### Protocol summary

##### Summary

In this investigation, the effects of a vaginal dosage form prepared from Gall and Myrtle in compression with placebo on bacterial vaginitis will be evaluated in a parallel study via double blind (patients and researchers) randomized clinical trial. Main inclusion criteria are patients between 18 and 55 years with symptoms of BV on clinical examination and tests and main exclusion criteria are positive clinical diagnosis but negative tests; pregnancy and breast feeding. Population study is patients coming to Motahari Polyclinic and request voluntary to include to the study. The number of subjects is 100 that we will include them randomly in to two groups with 50 persons. In one group, after take oral course of metronidazole and ensure the BV cure, subjects use vaginal dosage form. They use this drug sixteen nights. On the other hand, in the next group, patients use placebo with the same method. Then clinical examinations and tests will be repeated after 16 and 45 days. After applying drugs and gathering data, they will be analyzed

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016030526917N1**

Registration date: **2016-05-16, 1395/02/27**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-05-16, 1395/02/27

##### Registrant information

Name

Sayyede Fatemeh Askari

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Shiraz University of Medical Sciences

##### Expected recruitment start date

2016-09-19, 1395/06/29

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A vaginal dosage form preparation of Gall and Myrtle and study of their effects in bacterial vaginitis via double blind randomized clinical trial with placebo control

##### Public title

effect of Quercus brantii and Myrtus communis suppository on women infection

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Women aged 18-55 years, with signs on physical examination and tests, The lack of recent use of antiparasitic drugs, antibiotics, immunosuppressive

drugs and drugs during the past two weeks vaginal, No intercourse and no use of douching in last 48 hours, Lack of abnormal uterine bleeding, Non-pregnant and non-lactating, Not using douches repeatedly, No smoking or alcohol consumption and coumarin anticoagulants, Lack of sensitivity to drug components exclusion criteria: Taking any medication affecting drugs, Taking any drug effect on symptoms and treatment of vaginitis, Drug allergy, People who are considered patient based on the clinical diagnosis but based on test results are negative

#### Age

From **77 years** old to **40 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic Committee of Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences

##### City

Shiraz

##### Postal code

#### Approval date

2016-03-06, 1394/12/16

#### Ethics committee reference number

IR.SUMS.REC.1394.219

## Health conditions studied

### 1

#### Description of health condition studied

Bacterial Vaginitis

#### ICD-10 code

N76.8

#### ICD-10 code description

Other specified inflammation of vagina and vulva

## Primary outcomes

### 1

#### Description

Check cluecells

#### Timepoint

0, 16th, 45th after intervention

#### Method of measurement

counting by microscope

### 2

#### Description

determination the PpH of vagina

#### Timepoint

0, 16th, 45th after intervention

#### Method of measurement

by litmus paper with high precision

### 3

#### Description

Whiff test

#### Timepoint

0, 16th, 45th after intervention

#### Method of measurement

The smell of ammonia or fish from the discharge after the addition of KOH 10%

### 4

#### Description

Discharge color

#### Timepoint

0, 16th, 45th after intervention

#### Method of measurement

On examination it becomes clear to the eye.

### 5

#### Description

Nugnet score

#### Timepoint

0, 16th, 45th after intervention

#### Method of measurement

Using microbial count and Grading

## Secondary outcomes

### 1

#### Description

Microbial count for Candida albicans, Gardnerella morphotype, Mycoplasma hominis, Ureaplasma urealyticum, Trichomonas vaginalis

#### Timepoint

0, 16th, 45th after intervention

**Method of measurement**

counting by microscope

**Intervention groups****1****Description**

Suppositories prepared from the leaves of oak, For 16 nights

**Category**

Treatment - Drugs

**2****Description**

One placebo suppository,

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Motahari Polyclinic

**Full name of responsible person**

Dr. Bahya Namavar Jahromi

**Street address**

Namazi Square, Shiraz

**City**

Shiraz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Basir Hashemi

**Street address**

Research vice, 7th floor, Central building of Shiraz University of Medical sciences, Zand street, Shiraz

**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Shiraz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

**Person responsible for general inquiries****Contact****Name of organization / entity**

Traditional Persian Pharmacy Department, Faculty of Pharmacy, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Sayede Fatemeh Askari

**Position**

Pharm.D

**Other areas of specialty/work****Street address**

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Head of Traditional Persian Pharmacy Department

**Full name of responsible person**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*