

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation of the effect of oral *Myrtus communis* capsules in the treatment of vaginal candidiasis in patients referred to health- medical centers affiliated to Beheshti University of Medical Sciences, in 1391

#### Protocol summary

##### Summary

The present study has been conducted with the purpose of determination of the effect of oral *Myrtus communis* capsules in the treatment of vaginal candidiasis in referring to health- medical centers dependent to Beheshti University of Medical Sciences, in 1391. This study is performed as a double blind randomized clinical trial, among 100 married women 15-45 years with complains of vaginal itching or irritation. patients will be randomly divided into two groups: intervention (*Myrtus communis* capsules and Clotrimazole vaginal cream) and control (placebo and Clotrimazole vaginal cream). The patients use (500 mg capsules of *Myrtus communis* twice a day and clotrimazole vaginal cream 1 % one applicator of cream at bed time for one week) and the other group (500 mg capsules of starch powder twice a day with Clotrimazole vaginal cream 1%) over one weeks. Then patients will be checked 4- 7 days after completion of the treatment period and the side-effects will be registered. Data collection will accomplished demographic information questionnaire and clinical performance checklist, and these data will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201111264529N4**  
Registration date: **2013-07-14, 1392/04/23**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-07-14, 1392/04/23

##### Registrant information

##### Name

Nourossadat Kariman

##### Name of organization / entity

Shaheed Beheshti University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8888 3133

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2012-08-22, 1391/06/01

##### Expected recruitment end date

2013-08-23, 1392/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of oral *Myrtus communis* capsules in the treatment of vaginal candidiasis in patients referred to health- medical centers affiliated to Beheshti University of Medical Sciences, in 1391

##### Public title

Evaluating the effect of oral *Myrtus communis* capsules in the treatment of vaginal candidiasis

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

nclusion criteria: 1- Being married 2- Age between 15 or

453-Positive wet smear of vaginal discharge4- Not being pregnancy, lactation and menopausal period; Not having any vaginal bleeding5- Not having chorionic disease (diabetes, HIV,...) 6-Women that hadn't history of using antibiotic for 2 weeks before7-Women that don't use oral contraceptive pills 8-Not being overweight (Body Mass Index>29)9- Not having intercourse and vaginal douching during the last11 hours10- Not using any antifungal drugs, for 2 weeks before the study11-Not using vaginal cream for last 48 hours before the study12- Not having allergy with herbal drugs 13-only sexual partner 14- not having trichomonal vaginitis and bacterial vaginitis Exclusion criteria:1-druges intolerance .Having allergy with herbal drugs 2- pregnancy in study time 3- unwillingness to continue participation in this study 4- emergency use of antibiotic in study time 5- taking any other herbal remedy during the study 6- abnormal Pap smear results at 2 years 7-Failure to follow the correct method of treatment provided, taking more than one pill a day to forget and be forgotten vaginal cream more than one night

**Age**

From **15 years** old to **45 years** old

**Gender**

Female

**Phase**

2

**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**

Shaheed beheshti medical university, Dean of research

**Street address**

Tehran, Evin, Shaheed beheshti medical university

**City**

tehran

**Postal code**

-

**Approval date**

2012-09-16, 1391/06/26

**Ethics committee reference number**

122

**Health conditions studied****1****Description of health condition studied**

vaginal candidiasis

**ICD-10 code**

B37.3+

**ICD-10 code description**

Candidiasis of vulva and vagina

**Primary outcomes****1****Description**

Vaginitis

**Timepoint**

Four to 7 days after completion of the treatment period

**Method of measurement**

Accomplished demographic information questionnaire and clinical performance checklist, clinical observation-pH value vaginal discharge and direct microscopy examination

**Secondary outcomes**

empty

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

The patients in placebo group use 500 mg capsules of starch powder twice a day with clotrimazole vaginal cream1%.One applicator of cream use at bed time for one week

**Category**

Treatment - Drugs

**2****Description**

The patients in intervndtion group use 500 mg capsules of Myrtus communis twice a day with clotrimazole vaginal cream1 % One applicator of cream will be used at bed time for one week

**Category**

Treatment - Drugs

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

Hospital lolagar

**Full name of responsible person**

Fatemeh Rozbahani

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khosh streets - more than veterinary

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-

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-

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

shaheed beheshti medical university

**Full name of responsible person**

Dr.Massome Simbar

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Shahid Chamran highway- Yaman street- next to Taleghani hospital-Shahid Beheshti University of Medical Sciences

**City**

tehran

**Grant name****Grant code / Reference number**

-

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

Yes

**Title of funding source**

shaheed beheshti medical university

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Fatemeh Rozbahani

**Position**

Master of Midwifery

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**Web page address****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*