

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

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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

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Tehran, Evin, Shaheed beheshti medical university

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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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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

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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

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

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

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Person responsible for updating data**Contact****Name of organization / entity**

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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