Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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 cream1 % 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 cream1%) 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

n_kariman@sbmu.ac.ir

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 befor7-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 intulerance ،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 ofter 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 intervdntion 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
Street address
khosh streets - more than veterinary
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
shaheed beheshti medical university
Full name of responsible person
Dr.Massome Simbar
Street address
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
Other areas of specialty/work
Street address
Niayesh Street ,Shahid Beheshti Faculty of Nursing and Midwifery
City
Tehran
Postal code
-
Phone
+98 21 4469 1711
Fax
-
Email
rahgozar_gharib00@yahoo.com
Web page address
-

Person responsible for scientific inquiries

Contact
Name of organization / entity
shaheed beheshti medical university
Full name of responsible person
nourossadat kariman
Position
master of science in midwifery
Other areas of specialty/work
Street address
shaheed beheshti medical university
City
tehran
Postal code
-
Phone
+98 21 8820 2512
Fax
-
Email
n_kariman@sbmu.ac.ir
Web page address
-

Person responsible for updating data

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
Niayesh Street ,Shahid Beheshti Faculty of Nursing and Midwifery
City
Tehran
Postal code
Phone
+98 21 4469 1711
Fax
Email
rahgozar_gharib@yahoo.com
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