

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The comparison of the effect of oral Garlic tablets(Garsin); and Fluconazole in the treatment of vaginal candidiasis in women referred to Kuhdasht city health- medical centers in 1390

Protocol summary

Summary

Vaginitis is the most prevalent gynecological problem for women that look for treatment and is responsible for 10 millions physician visits annually. Use of herbal treatments has been recorded in many of patient groups as well as in general populations to increase health level. The present study has conducted with the purpose of determination and comparison of the effect of oral garlic tablets(garsin) and Fluconazole for the treatment of vaginal candidiasis in refferred women to Kuhdasht health medical center in 1390. This clinical trial is a prospective, multivariate, two-stage, two-group study in health medical centers in Kuhdasht in 2011 and it performs among 110 married women 18-44 years with complains of vaginal itching or irritation. Vulvovaginal candidiasis diagnoses through pH value vaginal discharge and direct microscopy examination and culture in agar sabouraud. Patients are divided to two randomized groups (55 members in each group) after exactly diagnose. patients in Garsin group and Fluconazole receive 3 doses 500mg Garsin tablet for 7 days and single dose 150 mg Fluconazole respectively .Then patients were checked 4-7 days after completion of the treatment period and the side-effects were registered. Data collection was accomplished demographic information questionnaire and clinical performance checklist, and these data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111193226N3**
Registration date: **2012-07-16, 1391/04/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-16, 1391/04/26

Registrant information

Name

Mahrokh Dolatian

Name of organization / entity

Shahid Beheshti University of Medical Scenices

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

m_dolatian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-02-25, 1390/12/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of oral Garlic tablets(Garsin); and Fluconazole in the treatment of vaginal candidiasis in women referred to Kuhdasht city health- medical centers in 1390

Public title

The effect of oral Garlic tablets(Garsin); and Fluconazole

in the treatment of vaginal candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women were 18-44 years old and were married; They had a single sexual partner and they themselves were the only sexual partner of their respective spouse; They had not used antibiotics, immunosuppressive drugs, or vaginal drugs 14 days before the study; They did not suffer from trichomonal vaginitis, bacterial vaginitis, or cervicitis based on direct smear, which was controlled by examining the patient's discharge; They were not at pregnancy or breast-feeding stage; They were not menopause (priority of not being menopause was higher than age criterion, i.e. They must have been non-menopause even if they were younger than 49 years old); They had not previously suffered from known medical diseases such as diabetes, immune system attenuating diseases (such as AIDS) or use of immunosuppressive drugs, auto-immune diseases, coagulation disorders, and epilepsy; They were not menstruated, and had no bleeding or breakthrough bleeding when they visited the clinics; candidiasis culture was in agreement with clinical symptoms and patient's complaints. Exclusion criteria: pregnancy in study time table; emergency use of antibiotic in study time and drug intolerance.

Age

From **18 years** old to **44 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Shahid Chamran highway- Yaman street- next to

Taleghani hospital-

City

Tehran

Postal code

1985717443

Approval date

2011-05-01, 1390/02/11

Ethics committee reference number

99

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

Intervention-3 doses 500mg meal Garsin tablet for 7 days

Category

Treatment - Drugs

2

Description

Control- single dose 150 mg Fluconazole meal capsule

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Rasoul Allah (PBUH) Hygienic and Medical Center

Full name of responsible person

Dr. Aminizade Hhasan

Street address

Clinical and treatment net of Kuhdasht- Farmandari square

City

Kuhdasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti 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

Clinical and treatment net

Full name of responsible person

Ebrahimi-Farzaneh

Position

Sc.midwifery

Other areas of specialty/work

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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