

# 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**

**Street address**

Farmandari square

**City**

Kuhdasht

**Postal code**

**Phone**

+98 66 3624 0671

**Fax**

**Email**

farzanehebrahimi@gmil.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dolatian Mahrokh

**Position**

Msc of Midwifery

**Other areas of specialty/work**

**Street address**

Vali asr street- Nyayesh junction- Shahid Beheshti University of Medical Sciences

**City**

Tehran

**Postal code**

**Phone**

+98 21 8820 2512

**Fax**

**Email**

mdolatian@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Clinical and Treatment Net

**Full name of responsible person**

Ebrahimi Farzaneh

**Position**

Sc of Midwifery

**Other areas of specialty/work**

**Street address**

Farmandari Squer

**City**

Kuhdasht

**Postal code**

**Phone**

00

**Fax**

**Email**

Farzanehebrahimi@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*