

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A comparative study of vaginal cream Clotrimazol and different dosage of vaginal ointment Myrtus on treatment of Candida Vaginitis in women refer to the Khoramabad Asali Hospital

#### Protocol summary

##### Summary

Objectives: The aim of this study is to compare the efficacy of two drugs, vaginal cream clotrimazol and different dosage of vaginal ointment myrtus (2.5%, 5% and 7%) on treatment of vaginal candidiasis. Objectives: The aim of this study is to compare the efficacy of two drugs, vaginal cream Clotrimazol and different dosage of vaginal ointment Myrtus (2.5%, 5% and 7%) on treatment of vaginal candidiasis Design: Prospective cohort study. Setting and conduct: 240 patients with positive culture of vaginal discharge due to candidiasis enrolled in this study. This study was conducted in Khoramabad Asali Hospital, Iran. Participants including major eligibility criteria: Inclusion criteria include 18-50 years women with positive culture of vaginal discharge due to candidiasis and exclusion criteria include of patients with Age less than 18 and more than 50 years old; pregnancy; diabetes; corticosteroid therapy and antibiotic therapy in two weeks ago. Intervention: The patients were randomly divided to four groups. Each group included 60 patients. Group A (received vaginal cream Clotrimazol1%), group B (received vaginal ointment Myrtus 2.5%), group C (received vaginal ointment Myrtus 5%) and group D received vaginal ointment Myrtus 7% for 7 days. Clinical symptoms of patients and microbiological evaluation before and after of treatment were prescribed. Main outcome measures (variables): The effect of different dosage of vaginal ointment Myrtus (2.5%, 5% and 7%) on treatment of vaginal candidiasis.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138810111744N4**  
Registration date: **2013-12-07, 1392/09/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-12-07, 1392/09/16

##### Registrant information

###### Name

Soheila Akbari

###### Name of organization / entity

Lorestan Medical Science University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 66 1225 0368

###### Email address

akbari.s@lums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Lorestan Khorraman Herb Company

##### Expected recruitment start date

2013-03-05, 1391/12/15

##### Expected recruitment end date

2013-06-21, 1392/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of vaginal cream Clotrimazol and different dosage of vaginal ointment Myrtus on treatment of Candida Vaginitis in women refer to the Khoramabad

Asali Hospital

## Public title

The effect of vaginal ointment Myrtus on Candida Vaginitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 18-50 years women with positive culture of vaginal discharge due to candidiasis Exclusion Criteria: Age less than 18 and more than 50 years old; pregnancy; diabetes; corticosteroid therapy and antibiotic therapy in two weeks ago.

## Age

From **18 years** old to **50 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

### 1

#### Registry name

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#### Secondary trial Id

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#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

##### Street address

Vice chancellor for research, Lorestan University of Medical Sciences, 3rd floor, Pardis(Kamalvand)University complex, 3 km. road Khoramabad Borojerd, Khoramabad

##### City

Khoramabad

## Postal code

381351698

## Approval date

2012-12-29, 1391/10/09

## Ethics committee reference number

79123/200

## Health conditions studied

### 1

#### Description of health condition studied

candidiasis vaginitis

#### ICD-10 code

n76.0

#### ICD-10 code description

Acute vaginitis

## Primary outcomes

### 1

#### Description

The assay of effective dosage of vaginal ointment of Myrtus on treatment of candidiasis vaginitis

#### Timepoint

Before and a week after of tial

#### Method of measurement

Questioner, examination and culture of vaginal discharge

## Secondary outcomes

### 1

#### Description

Failure of treatment

#### Timepoint

A week after trial

#### Method of measurement

Questioner, examination and culture of vaginal discharge

## Intervention groups

### 1

#### Description

The patients with candidiasis vaginitis were treated with vaginal cream Clotrimazol 1% for a week.Improvement of clinical symptoms and microbiological evaluations were carried out.

#### Category

Treatment - Drugs

### 2

#### Description

The patients with candidiasis vaginitis were treated with vaginal ointment Myrtus 2.5% for a week. Improvement of clinical symptoms and microbiological evaluations were carried out.

#### Category

Treatment - Drugs

### 3

#### Description

The patients with candidiasis vaginitis were treated with vaginal ointment Myrtus 5% for a week. Improvement of clinical symptoms and microbiological evaluations were carried out.

#### Category

Treatment - Drugs

### 4

#### Description

The patients with candidiasis vaginitis were treated with vaginal ointment Myrtus 7% for a week. Improvement of clinical symptoms and microbiological evaluations were carried out.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Lorestan University of Medical Sciences

##### Full name of responsible person

Soheila Akbari

##### Street address

Lorestan University of Medical Sciences,  
Pardis(Kamalvand) university complex, 3 km. road  
Khoramabad Borojerd, Khoramabad

##### City

Khoramabad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Lorestan University of  
Medical Sciences

##### Full name of responsible person

dr Mohammad hasan Kaedi

##### Street address

Vice chancellor for research, Lorestan University of  
Medical Sciences, 3rd floor,  
Pardis(Kamalvand)University complex, 3 km. road  
Khoramabad Borojerd, Khoramabad

##### City

Khoramabad

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice chancellor for research, Lorestan University of

Medical Sciences

##### Proportion provided by this source

##### 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

### 2

#### Sponsor

##### Name of organization / entity

khorraman herbal company

##### Full name of responsible person

dr. ali saleh

##### Street address

Industrial Estate No.1, khorramabad

##### City

khorraramabad

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

khorraman herbal company

##### Proportion provided by this source

##### 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

Lorestan University of Medical Sciences

##### Full name of responsible person

Akbari Soheila

##### Position

Obstetric and Gynecologist

##### Other areas of specialty/work

##### Street address

Unit 5, 3rd floor, Yas bldg, Laleh St. Jandarmery Sq.  
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**Email**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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

Lorestan University of Medical Sciences

**Full name of responsible person**

Akbari Soheila

**Position**

Obstetric and Gynecologist

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

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+98 66 1225 0368

**Email**

dr\_akbari\_s@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*