

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical Effects of Chlorhexidine Vaginal Gel in the Treatment of Vaginal Infections

#### Protocol summary

##### Summary

Determine the Clinical Effects of Chlorhexidine Vaginal Gel in the Treatment of Vaginal Infections. This Study is Double-Blind Clinical Trial That Randomly Drug is Delivered to Patients. The First Step is aking the formulation. The new Drug formulation, Chlorhexidine Vaginal Gel in Pharmaceuticals Laboratory in Aseptic Conditions and Then Packaging and labeling is taken. Second the Step the Patients will Examine then are Placed in three Groups: Vaginal Candidiasis, Bacterial Vaginosis, Unspecific Vaginitis. In the first Group with Vaginal Clotrimazole (1a) or a Vaginal Gel Chlorhexidine (1 b), The second Group of Metronidazole Vaginal Cream (2 a) or Chlorhexidine Vaginal Gel (2 b), Third Group clotrimazole Vaginal with Metronidazole (3a) or Chlorhexidine Vaginal Gel (3 b) prescribed. Vaginal Ointment at Bedtime an Applicator to five Days and Metronidazole 500 mg every 12 hours to five days. To better Evaluate the Therapeutic effects and Potential Drug side effects in addition to the completion of Drug use (after five days), two and three weeks after Treatment to Evaluate the visit.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2016070428780N1**  
Registration date: **2017-02-08, 1395/11/20**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-08, 1395/11/20

##### Registrant information

##### Name

Maryam Zangene

##### Name of organization / entity

Kermanshah University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 918 832 3419

##### Email address

ma\_zangeneh@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kermanshah University of Medical Sciences

##### Expected recruitment start date

2016-06-25, 1395/04/05

##### Expected recruitment end date

2017-03-25, 1396/01/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical Effects of Chlorhexidine Vaginal Gel in the Treatment of Vaginal Infections

##### Public title

Treatment of Vaginal Infections

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

List Inclusion and Exclusion criteria separately (Inclusion Criteria: Women Before the age of Menopause and Non-pregnant; with Abnormal Vaginal Discharge; Without Underlying Disease Such as Diabetes; Without Immunosuppressive Drugs; Cervicitis and Excluded criteria: There are no Specific Criteria)

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **102**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

-

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kermanshah University of Medical Sciences

##### Street address

Kermanshah, Ave shahid beheshti. Building No. 2

##### City

Kermanshah

##### Postal code

-

#### Approval date

2016-06-25, 1395/04/05

#### Ethics committee reference number

Kums.rct.1395.218

## Health conditions studied

### 1

#### Description of health condition studied

Vaginal Infection

#### ICD-10 code

N74\*

#### ICD-10 code description

Female pelvic inflammatory disorders in diseases classified elsewhere

## Primary outcomes

### 1

#### Description

Vaginitis

#### Timepoint

A week after Intervention

#### Method of measurement

Physical Examination and the Patient's Scoring

## Secondary outcomes

### 1

#### Description

Vaginal Irritation

#### Timepoint

Within a Week

#### Method of measurement

Question

### 2

#### Description

Nausea

#### Timepoint

Within a Week

#### Method of measurement

Question

### 3

#### Description

Vomiting

#### Timepoint

Within a Week

#### Method of measurement

Question

## Intervention groups

### 1

#### Description

The Third Group Included Patients with Concurrency both Vaginitis. For 5 days, one day in between , Clotrimazole Vaginal with Metronidazole or Chlorhexidine Vaginal Gel is Prescribed. In order to better Evaluate the Therapeutic Effects and Potential Drug side Effects, two and three weeks after Treatment, one day Patients refer to Hospital for Visited again.

#### Category

Treatment - Drugs

### 2

#### Description

The Second Group Included Patients are Bacterial Vaginosis. For 5 days, one day in Between , Metronidazole Vaginal Cream or Chlorhexidine Vaginal Gel is Prescribed. In order to better evaluate the therapeutic effects and Potential Drug side Effects, two and three weeks after Treatment, one day Patients refer to Hospital for Visited again.

**Category**

Treatment - Drugs

**3****Description**

The First Group Included Patients with Vaginal Candidiasis. For 5 days, one day in between , Clotrimazole Vaginal Cream or Vaginal Gel Chlorhexidine is prescribed. In order to better evaluate the Therapeutic effects and Potential drug side Effects, two and three weeks after Treatment, one day patients refer to Hospital for Visited again.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Reza Teaching Hospital

**Full name of responsible person**

Dr.Somaye Parsa

**Street address**

Kermanshah, Sorkhalyzhe, Imam Reza Teaching Hospital

**City**

Kermanshah

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice Chancellor for Research and Technology  
Kermanshah University of Medical Sciences**Full name of responsible person**

Dr .Behrooz Hamzeh

**Street address**Kermanshah, Shahid Beheshti Blvd., Building No.  
2,Vice Chancellor for Research and Technology**City**

Kermanshah

**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 and Technology  
Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr Somaye Parsa

**Position**

Resident of Obstetrics and Gynecology

**Other areas of specialty/work****Street address**Kermanshah University of Medical Sciences Sorkhe  
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**Full name of responsible person**

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**Full name of responsible person**

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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*