

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Clinical Trial of Comparison the Effect of Gynophilus Vaginal Capsule and Clindamycine Gel on Treatment of Bacterial Vaginosis among Pregnant Women under 20 Weeks of Gestation

#### Protocol summary

2014-06-29, 1393/04/08

#### Summary

The Aim of This Study is to Compare the Effect of Gynophilus Vaginal Capsule and Clindamycin Gel on Treatment of Bacterial Vaginosis among Pregnant Women under 20 Weeks of Gestation Referred to Sayad-Shirazi Tertiary Hospital. Inclusion Criteria Include Pregnant women under 20 Weeks of Gestation with Bacterial Vaginosis, Filing the Informed Consent Form and No Vaginal Bleeding and Exclusion Criteria include No Tendency to Participate in the Study after Entering to the Study, Incomplete Consumption of Medications and No Referring for Second and Third Examinations. In This Single Blind Study, 150 Women with Bacterial Vaginosis Will Be Assigned to Two Groups of 75 Women by Simple Random Allocation. Gynophilus Vaginal Capsule Containing 341 mg Will Be Prescribed for Intervention Group, Twice a Day for 7 days and Clindamycin Vaginal Gel Will Be Prescribed 5 gm Once a Day for 7 Days. Then, Samples will Be Evaluated for Recurrence of Disease after 7 Days and 1 Month Later. Moreover, All These Women Will Be Followed until Delivery and They Will Be Evaluated for Preterm Labor and Premature Rupture of Membrane (PROM) and Their Neonate will be evaluated for Birth Weight and APGAR Score at 1st and 5th Minute of Birth.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014040817167N1**

Registration date: **2014-06-29, 1393/04/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

#### Registrant information

##### Name

soudeh ramazanpour

##### Name of organization / entity

golestan medical university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3372 3054

##### Email address

dr.ramazanpour@goums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Golestan University of Medical Sciences

#### Expected recruitment start date

2013-12-22, 1392/10/01

#### Expected recruitment end date

2014-06-22, 1393/04/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Clinical Trial of Comparison the Effect of Gynophilus Vaginal Capsule and Clindamycine Gel on Treatment of Bacterial Vaginosis among Pregnant Women under 20 Weeks of Gestation

#### Public title

Effect of Gynophilus Capsule on Treatment of Bacterial Vaginosis (BV)

#### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion Criteria: Pregnant Women under 20 Weeks` Gestation with Bacterial Vaginosis; Filing the Informed Consent Form; No Vaginal Bleeding. Exclusion Criteria: No Tendency to Participate in the Study after Entering to the Study; Incomplete Consumption of Medications; No Referring for Second or Third Examinations.

### **Age**

No age limit

### **Gender**

Female

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **150**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Golestan University of Medical Sciences

##### **Street address**

Shastkola Road, Golestan University of Medical Sciences, Gorgan, Iran

##### **City**

Gorgan

##### **Postal code**

#### **Approval date**

2013-12-22, 1392/10/01

#### **Ethics committee reference number**

23279208121

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Bacterial Vaginosis

#### **ICD-10 code**

N76

#### **ICD-10 code description**

Other inflammation of vagina and vulva

## **Primary outcomes**

### 1

#### **Description**

Recurrence

#### **Timepoint**

One Month after Treatment

#### **Method of measurement**

AMSEL Criteria

### 2

#### **Description**

Cure

#### **Timepoint**

One Week after Treatment

#### **Method of measurement**

AMSEL Criteria

## **Secondary outcomes**

### 1

#### **Description**

Premature Rupture of Membrane

#### **Timepoint**

Total Duration of Pregnancy

#### **Method of measurement**

Gestational Age Less Than 37 Weeks

### 2

#### **Description**

Preterm labor

#### **Timepoint**

Total Duration of Pregnancy

#### **Method of measurement**

Gestational Age Less Than 37 Weeks

### 3

#### **Description**

Neonate`s APGAR score

#### **Timepoint**

First and Ffth Minute of Birth

#### **Method of measurement**

APGAR Score Table

### 4

#### **Description**

Birth Weight of Neonate

#### **Timepoint**

After Birth

#### **Method of measurement**

Scale

## Intervention groups

### 1

#### Description

Intervention: Administration of Gynophilus Vaginal Capsule, Containing of 341 mg, Twice a Day, For 7 Days.

#### Category

Treatment - Drugs

### 2

#### Description

Control: Administration of Clindamycin Vaginal Gel, One Applicator about to 5 mg, Once a Day, for 7 Days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sayad Shirazi Tertiary Hospital

##### Full name of responsible person

Soudeh Ramazanpour

##### Street address

Sayad Shirazi Bulvar, Sayad Shirazi Tertiary Hospital, Gorgan,Iran

##### City

Gorgan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Golestan University of Medical Sciences

##### Full name of responsible person

Dr. Masoud Khoshnia

##### Street address

Shstkola Road, Golestan University of Medical Sciences, Gorgan, Iran.

##### City

Gorgan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Golestan 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

Golestan University of Medical Sciences

##### Full name of responsible person

Dr. Soudeh Ramazanpour

##### Position

Assistant of Gynecology

##### Other areas of specialty/work

##### Street address

Sayad Shirazi Bulvar, Sayad Shirazi Tertiary Hospital, Gorgan, Iran.

##### City

Gorgan

##### Postal code

##### Phone

+1 733723054

##### Fax

##### Email

dr.ramazanpour@goums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Golestan University of Medical Sciences

##### Full name of responsible person

Dr. Azamosadat fayazi

##### Position

Obstetrics and Gynecology Specialist

##### Other areas of specialty/work

##### Street address

Sayad Shirazi Bulvar, Sayad Shirazi Tertiary Hospital, Gorgan, Iran.

##### City

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##### Postal code

##### Phone

+98 17 1442 1651

##### Fax

##### Email

faiazay@yahoo.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Golestan University of Medical Sciences

##### Full name of responsible person

Dr. Soudeh Ramazanpour

##### Position

Assistant of Gynecology

##### Other areas of specialty/work

##### Street address

Sayad Shirazi Bulvar, Sayad Shirazi Tertiary Hospital,  
Gorgan, Iran.

**City**

Gorgan

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**Phone**

**Fax**

**Email**

dr.ramazanpour@goums.ac.ir

**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*