

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

Gorgan

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

Postal code

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