

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

A comparative study of the therapeutic effect of the propolis vaginal cream and metronidazol vaginal gel on bacterial vaginosis in reproductive aged women

Protocol summary

Summary

This study will carry out to compare the effect of Propolis vaginal cream with metronidazol vaginal gel on the treatment results of bacterial vaginitis . This clinical trial will conduct on 100 reproductive aged women for a period of 10 months .They will divide into two groups of 50 subjects(Metronidazol and Propolis) by randomized allocation method. all the patients will apply the drug once a day for 10 days only. The results will compare after 10 days of therapy with respect to nugent score changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408202325N2**
Registration date: **2014-09-09, 1393/06/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-09, 1393/06/18

Registrant information

Name

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Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research of Islamic Azad University of Isfahan (Khorasgan Branch)

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the therapeutic effect of the propolis vaginal cream and metronidazol vaginal gel on bacterial vaginosis in reproductive aged women

Public title

A comparative study of the therapeutic effect of the propolis vaginal cream and metronidazol vaginal gel on bacterial vaginosis in reproductive aged women referring to gynecology clinics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: willingness to participate; reproductive age (between 18 years ; premenopause age. Exclusion Criteria: pregnancy; breast feeding; using hormonal or immunosuppressive drugs; having sexually transmitted and autoimmune diseases or allergy; using antibiotics or vaginal drugs during two weeks prior to the study; using other supportive treatments like vaginal douche at the time of drug application.

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

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**

Isfahan University of Medical Sciences

Street address

Isfahan, Hezarjarib St. Vice chancellor for
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Postal code

81745319

Approval date

2013-06-22, 1392/04/01

Ethics committee reference number

492013

Health conditions studied**1****Description of health condition studied**

Bacterial Vaginosis

ICD-10 code

N76.0

ICD-10 code description

Acute vaginitis

Primary outcomes**1****Description**

Therapeutic effect of bacterial vaginosis

Timepoint

10 days

Method of measurement

Gram Stain

Secondary outcomes**1****Description**

Vaginal Itching

Timepoint

After 10 days

Method of measurement

Questionnaire

Intervention groups**1****Description**

All the patients have the Amsels criteria and positive gram stain. They will divide into two groups of 50 subjects (Metronidazol vaginal gel and Propolis vaginal cream) by randomized allocation method. In intervention group patients will use one applicator of propolis vaginal cream of 7.5 % once a day for 10 days only.

Category

Treatment - Drugs

2**Description**

In control group patients will apply the metronidazol vaginal gel once a day for 10 days only. The results will compare after 10 days of therapy with respect to Nugent score changes.

Category

Treatment - Drugs

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

Gynecology clinic of Zeinabieh hospital

Full name of responsible person**Street address****City**

shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University of Isfahan (Khorasgan Branch)

Full name of responsible person

Mahsa Sadat Mousavi

Street address

Isfahan,Jey St
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University of Isfahan(Khorasgan Branch)
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

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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