Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Mahsa Sadat Mousavi

Name of organization / entity

Khorasgan (Isfahan) Branch, Islamic Azad University, Isfahan, Iran

Country

Iran (Islamic Republic of)

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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 Research,Isfahan University of Medical Sciences
City
Isfahan
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
Questionnair

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 aplicator 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

Name of organization / entity

Islamic Azad University of Isfahan(Khorasgan Branch)

Full name of responsible person

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Position

Instructor

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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