

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the vaginal tablet of vagiclean and metronidazole on Bacterial vaginosis

Protocol summary

Study aim

- Determination and comparison of the frequency of positive Amsel criteria (KOH test, PH test, presence of clinical symptoms, smear test) before and after treatment in two groups - Comparison of frequency of complications and complaints (inflammatory and allergic reactions, dryness, itching) of patients after treatment and comparison of two groups

Design

This study is the third phase of a triple-blind randomized clinical trial that will be conducted on 106 female patients with bacterial vaginosis. The selection of samples from medical centers and obstetrics and gynecology clinics will be convenience, and the allocation of patients to treatment groups will be done by permuted block randomization that used as DOE option in MINITAB software version 15. The treatment period will be 10 days and one pill every day.

Settings and conduct

The study will be conducted on a female patient suffering from bacterial vaginosis, referring to medical centers and specialized gynecology and obstetrics clinics.

Participants/Inclusion and exclusion criteria

- Women aged 18 to 49 who are sexually active
- Bacterial vaginitis has been diagnosed in them. Proof of bacterial vaginosis in the studied units will be based on Amsel criteria, which has at least 3 of the following 4 cases: 1. Uniform white-yellowish-gray vaginal discharge 2. Vaginal pH greater than 4.5 3. Wif positive test 4. The presence of key cells in the wet smear sample

Intervention groups

The intervention group consisted of recipients of vagiclean vaginal tablets The control group included the recipients of metronidazole vaginal tablets

Main outcome variables

The result of the wet mount test KOH test result Amsel criteria The symptoms of the disease include vaginal discharge, foul-smelling discharge, itching, pain during intercourse, burning, urinary burning and Lower

abdominal pain

General information

Reason for update

Acronym

Vagiclean

IRCT registration information

IRCT registration number: **IRCT20220512054829N1**

Registration date: **2022-09-19, 1401/06/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-19, 1401/06/28**

Update count: **0**

Registration date

2022-09-19, 1401/06/28

Registrant information

Name

Hossein Akbari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-21, 1401/02/31

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the vaginal tablet of vagiclean and metronidazole on Bacterial vaginosis

Public title

Comparison of the vaginal tablet of vagiclean and metronidazole on Bacterial vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

• Women in the age range of 18 to 49 years • Women who are sexually active • Bacterial vaginitis has been diagnosed in them.

Exclusion criteria:

• Pregnancy and lactation • The presence of an intrauterine device , Use of specific medications such as immunosuppressive drugs and broad-spectrum antibiotics • Having certain diseases such as liver, nerve, heart, kidney and blood dyscrasias and diabetes Use of antiprostaglandins • Complications from drug use or drug allergies • Vaginal candidiasis and Trichomonas vaginalis

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by permuted block method so that first all 4 blocks which include two codes A and B (6 blocks) are prepared and numbers from one to 6 are assigned to each. Then, using the table of random numbers of each number 1 to 6 that is selected, the corresponding block of each code will be written (30 blocks). Based on this, a sequence of codes A and B with 80 codes (proportional to the number of samples) is prepared. Then, each of the letters A and B is randomly assigned to one of the drug and placebo groups. The same code is recorded on each drug and will remain with the formulation department until the end of the study. At the end of the study, the drug code in the form of A and B will be provided to the statistical analyst. In this way, both randomization of the study and three-way blinding will be performed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drugs in both groups are in the form of vaginal tablets and are packaged in one-size-fits-all vials in the formulation section of Barij Essential Oil Pharmaceutical Company, then coded based on codes previously prepared using a random number table.

Placebo

Not used

Assignment

Parallel

Other design features

Considering that the treatment period of metronidazole for the treatment of bacterial vaginosis is 5 days and the treatment period of Vagiclean is 10 days. Patients of the first group who will be treated with vagiclean vaginal tablets. These tablets are in two packages of five vials, which are placed on one of the vials marked 'for use for the first five days' and on the other vial marked 'for use on the second five days'. In this way, the patients of the case group receive medicine for ten days. But in metronidazole group, patients receive placebo for 5 days. The purpose of this work was to perform complete blinding.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Biomedical Research, Kashan University of Medical Sciences

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Isfahan

Postal code

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Approval date

2022-05-14, 1401/02/24

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1400.211

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

Bacterial vaginosis

ICD-10 code

N70-N77

ICD-10 code description

Inflammatory diseases of female pelvic organs

Primary outcomes

1

Description

bacterial vaginitis

Timepoint

Before intervention, 5th days of intervention, 10th days of intervention

Method of measurement

Observation of symptoms

2

Description

Clinical symptoms (dysuria, itching, lower abdominal pain, burning, dysparonia, foul-smelling discharge, vaginal discharge)

Timepoint

Before intervention, 5th days of intervention, 10th days of intervention

Method of measurement

Observation of symptoms

3

Description

Positive Amsel criteria (KOH test, PH test, clinical signs, smear test)

Timepoint

Before intervention, 5th days of intervention, 10th days of intervention

Method of measurement

results of laboratory symptoms

Secondary outcomes

1

Description

Dysuria, itching, lower abdominal pain, burning, dysparonia, foul-smelling discharge, vaginal discharge

Timepoint

Before intervention, 5th day of intervention, 10th day of intervention

Method of measurement

Clinical interview with the patient

2

Description

Positive Amsel criteria (KOH test, PH test, clinical signs, smear test)

Timepoint

Before intervention, 5th day of intervention, 10th day of intervention

Method of measurement

Observation of symptoms

Intervention groups

1

Description

Intervention group: Vagiclean vaginal tablets

Category

Treatment - Drugs

2

Description

Control group: Metronidazole vaginal tablets

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti hospital of kashan

Full name of responsible person

Hossein Akbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

No

Title of funding source

Barij essnce pharmaceutical company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Industry

Person responsible for general inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Hossein Akbari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

It is possible to share some of the data

When the data will become available and for how long

The access period begins one year after the publication

of the article

To whom data/document is available

All faculty members of medical universities

Under which criteria data/document could be used

If they want to do more accurate statistical analysis on the data or use newer diagnostic methods to measure the outcome of the intervention

From where data/document is obtainable

Call phon and email

What processes are involved for a request to access data/document

By making a phone call or e-mail to the responsible person and concluding a memorandum of cooperation about the service that is to be provided and the benefit that will reach the parties

Comments