

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effectiveness of traditional medicine product and metronidazole vaginal gel in the treatment and prevention of recurrence in patients with bacterial vaginosis

Protocol summary

Study aim

Comparison of the effectiveness of traditional medicine product and metronidazole vaginal gel in the treatment and prevention of recurrence in patients with bacterial vaginosis

Design

The two-group clinical trial, with a control group, with parallel groups, triple blind, randomized, phase 2 with 60 patients. Randomization.com is used for randomization.

Settings and conduct

In this study, 60 women aged 18-50 years referred to gynecological clinics affiliated to Mashhad University of Medical Sciences, which were approved according to the criteria of bacterial vaginosis. The study is three-blind. Capsules and tubes of the same shape are placed in the same number in similarly numbered envelopes and therefore participants, researchers, data analysts are unaware of the intervention and control groups. Only the sample allocator to the groups is aware of the control and intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married non-pregnant and non-lactating women; 15 -44 Years old; Positive at least 3 out of 4 Amsel criteria. Non-inclusion criteria: Use of antibiotics in the last 4 weeks; Known chronic diseases; Taking coumarin anticoagulants; Diarrhea

Intervention groups

Intervention group: 10% rhubarb Vaginal Gel and Oral Capsule containing 200 mg of rhubarb Extract for a week. Control group: Metronidazole 0.75 mg Vaginal gel and placebo capsule for a week

Main outcome variables

Vaginal discharge; Vaginal acidity; Whiff test; Clue cells

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200926048840N1**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

sedighe mousaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3884 8931

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-12, 1400/07/20

Expected recruitment end date

2021-12-23, 1400/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of traditional medicine

product and metronidazole vaginal gel in the treatment and prevention of recurrence in patients with bacterial vaginosis

Public title

Effect of Persian medicine product on the recovery and relapse of bacterial vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women 18 -50 years old Positive at least 3 out of 4 Amsel criteria

Exclusion criteria:

Pregnancy Lactation Menopause Vaginal bleeding Use of antibiotics in the last 4 weeks Known chronic diseases Using oral contraceptives to prevent pregnancy Smoking and Consuming alcohol Using Coumarin anticoagulants Multiple sexual partners Diarrhea

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

We prepare 60 envelopes and numbers from one to 60. We prepare and print random numbers with the help of the Randomaize.com site and put them inside the envelopes. Capsules and tubes with the same shape and same number are put in the same envelopes based on a random allocation list by a person outside the research project. We ask patients to choose an envelope containing a number and to receive the relevant medicine envelope according to the number

Blinding (investigator's opinion)

Triple blinded

Blinding description

The capsules and tubes in the same shape and number are placed in numbered envelopes and therefore participants, researchers and data analysts are unaware of the intervention and control groups. Only the sample allocator to the groups is aware of the control and intervention group

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad University Of Medical Sciences, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2020-09-12, 1399/06/22

Ethics committee reference number

IR.MUMS.REC.1399.429

Health conditions studied

1

Description of health condition studied

Bacterial vaginosis

ICD-10 code

Acute vagi

ICD-10 code description

N76.0

Primary outcomes

1

Description

Cure (Elimination of all Amsel criteria or remaining only one criterion and according to the agent scoring system, a score of 1 to 3 or 4 to 6 without key cells)

Timepoint

10 days after the start of treatment and 30 days after the end of treatment

Method of measurement

Amsel and Najnat criteria

Secondary outcomes

1

Description

Vaginal discharge

Timepoint

10 days after the start of treatment and 30 days after the end of treatment

Method of measurement

observation

2

Description

Vaginal acidity

Timepoint

10 days after the start of treatment and 30 days after the end of treatment

Method of measurement

Ph strip

3

Description

Whiff test

Timepoint

10 days after the start of treatment and 30 days after the end of treatment

Method of measurement

Koh 10% solution

4

Description

Clue cells

Timepoint

10 days after the start of treatment and 30 days after the end of treatment

Method of measurement

Evaluation of clue cells in the wet lam

5

Description

Nagnet score

Timepoint

10 days after the start of treatment and 30 days after the end of treatment

Method of measurement

Evaluation of stained slide

Intervention groups

1

Description

Intervention group: 10% vaginal gel prepared from aqueous extract of rhubarb root and oral capsule containing 200 mg of aqueous extract of rhubarb root will be used for a week to treat bacterial vaginosis.

Category

Treatment - Drugs

2

Description

Control group: Vaginal gel 0.75% metronidazole and placebo capsules will be used by the samples for a week to treat bacterial vaginosis

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Malihe Afiat

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Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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<http://v-research.mums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sedigheh Moosaei
Position
PhD candidate in Iranian Traditional and Complementary Medicine
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Person responsible for updating data

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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

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

Analytic Code

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

Data Dictionary

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