Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

Phone
+98 51 3884 8931

Email address
mousaeis941@mums.ac.ir

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
Street address
Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2609
Email
afiatm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Research and Technology Vice-Chancellory of Mashhad University of Medical Sciences, Qureshi Building, Daneshgah Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Phone
+98 51 3841 2081
Email
vcresearch@mums.ac.ir
Web page address
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

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

School of Traditional and Compelementary Medicine, Ferdosi University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3884 8931

Email

Mousaeis941@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Motavasselian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Mashhad Faculty of Iranian and Complementary Medicine, East Door, University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3884 8930

Email

MotavasselianM@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sedighe Mousaei

Position

Persian Traditional Medicine Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Mashhad Faculty of Iranian and Complementary Medicine, East Door, University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3884 8931

Fax

Email

mousaeis941@mums.ac.ir

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