

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Effect of Vaginal Cream of Aqueous Extract from Aerial Part Scrophularia Striata on Bacterial Vaginitis in Married Women with Aged 18 to 45 Years: a Triple Blind, Randomized, Controlled Clinical Trial

Protocol summary

Study aim

Investigating the effect of vaginal cream of aqueous extract of the scrophularia striata plant on bacterial vaginosis

Design

Clinical trial with control group with parallel groups three_way blind randomized phase 3 on 120 patients. A tablet of random numbers is used for randomization.

Settings and conduct

This study will be conducted in the form of a three blind controlled clinical trial with the aim of investigating the effect of the vaginal cream of the aqueous extract of the scrophularia striata plant on bacterial vaginitis infections during 1402. they refer to the women department of Shahid Rahimi Hospital in Khorramabad city for treatment and meet the conditions for entering the study based on the mentioned criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women in the age range of 18 to 45 years, being married, having at least 3 of the 4 amsel criteria, having informed consent, BMI less than 30
Exclusion criteria: Inability of the patient to complete the treatment protocol, presence of other vaginitis along with bacterial vaginitis, the patients lack of consent to continue participating in the study, pregnancy, abnormal vaginal bleeding, other systemic diseases, history of smoking drugs alcohol, use of cryotherapy during the six weeks before the study, history of frequent infections (4 or more than 4 times a year), history of allergy to medicinal herbs and metronidazol, using antibiotics in the last two weeks, using vaginal creams suppositories or shower in the last 48 hours

Intervention groups

Intervention group: Metronidazol gel plus vaginal cream containing Scrophularia Striata plant extract control group: Metronidazol gel plus placebo vaginal cream

Main outcome variables

Examination of clinical symptoms of vaginal burning, vaginal itching, pain during intercourse, examination of Amsels clinical criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200721048159N7**

Registration date: **2023-08-16, 1402/05/25**

Registration timing: **prospective**

Last update: **2023-08-16, 1402/05/25**

Update count: **0**

Registration date

2023-08-16, 1402/05/25

Registrant information

Name

Forouzan Ahmadpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3312 0239

Email address

ahmadpour.f@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-02-17, 1402/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Vaginal Cream of Aqueous Extract from Aerial Part Scrophularia Striata on Bacterial Vaginitis in Married Women with Aged 18 to 45 Years: a Triple Blind, Randomized, Controlled Clinical Trial

Public title

Evaluation of the Effect of Scrophularia Striata Extract on Bacterial Vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women in the age range of 18 to 45 years Being married Having at least 3 of the 4 amsel criteria Having informed consent BMI less than 30

Exclusion criteria:

Inability of the patient to complete the treatment protocol presence if other vaginitis along with bacterial vaginitis The patients lack of consent to continue participating in the study Abnormal vaginal bleeding Pregnancy Other systemic diseases History of smoking, drugs or alcohol Use of cryotherapy during the six weeks before the study History of frequent infections (4 or more than 4 times a year) History of allergy to medicinal herbs and metronidazol Using antibiotics in the last two weeks Using vaginal creams, suppositories or shower in the last 48 hours

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected consecutively and easily from the eligible people of the studied community and will be assigned to the fore studied groups using the random block method. This method is used to avoid significant imbalances in the number of participants assigned to each group. Block randomization guarantees that there is no significant imbalance between the groups during randomization, and at certain points the number of participants in each group is equal. For this method, the size of each block must be determined first (example block of four). Then write the list of blocks and assign numbers to them (AABB(1)-ABAB(2)-ABBA(3)-

BBAA(4)-BABA(5)-BAAB(6)) Then choose random number between 1 and 6 (for example, 1,4,5 and...) and finally specifying the treatment allocation list based on the previous random numbers(AABB-BBAA-BABA...).

Blinding (investigator's opinion)

Triple blinded

Blinding description

The sample will be studied in a three-way blind way, so that the patient, the researcher, and the statistical analyst will not know which they are in arm. In this study, each group of drugs will be specified as boxes A and B will be provided to the researcher, and patient will randomly choose one of the boxes after visiting.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Lorestan University of Medical Sciences

Street address

Office of Research Ethics Committee, Vice Chancellor for Research and Technology, Lorestan University of Medical Sciences, Pardis University Complex, 3 km of Khorramabad Road, Khorramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

6813816314

Approval date

2023-01-18, 1401/10/28

Ethics committee reference number

IR.LUMS.REC.1402.118

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

Bacterial vaginitis

ICD-10 code

N76.0

ICD-10 code description

Acute vaginitis

Primary outcomes

1

Description

Evaluation of Amsels clinical criteria

Timepoint

Evaluation of clinical symptoms based on the Amsels criteria at the beginning of the study and 2 to 7 days after the end of the treatment period

Method of measurement

Patient examination and sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They uses 0/75% metronidazol vaginal gel along with vaginal cream containing 5% aqueous extract of the Scrophularia Striata plant for 5 day and 12 hours apart.

Category

Treatment - Drugs

2

Description

Control group: they uses 0/75% metronidazol vaginal gel along with placebo vaginal cream for 5 day and 12 hours apart.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahimi Hospital

Full name of responsible person

Forouzan Ahmadpour

Street address

Shahid Seyed Fakhreddin Rahimi Hospital, not far from Safavid Bridge, Mojahedin Street, Azadi Square

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Khorramabad

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ahmadpourforoz@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Street address

Lorestan University of Medical Sciences, Pardis University Complex, 3 km of Khorramabad Road, Khorramabad, Lorestan, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Position

Assistant professor of clinical pharmacy

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Lorestan University of Medical Sciences, Pardis University Complex, 3 km of Khorramabad Road, Khorramabad, Lorestan, Iran

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Position

Assistant professor of clinical pharmacy

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Position

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not 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