Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 bactrial 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 scrofularia 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 if 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 cryothetapy 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

ahmadpoor.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 cryothetapy 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 is 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 th ey 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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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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Person responsible for updating data

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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