Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of vaginal preparation on the basis of traditional medicine (containing masoids and zeinans) on the recovery and relapse of bacterial vaginitis and trichomoniasis

Protocol summary

Study aim

The aim of this study was to investigate the effect of vaginal preparation on the basis of traditional medicine (including masoids and zeinans) on the recovery and relapse of bacterial vaginitis and trichomoniasis.

Design

This project was a clinical trial with a control group, with parallel groups, double blind, Simply randomized by using random numbers table, Phase 3 clinical trial and the predicted sample size is 40.

Settings and conduct

This project is done at the office of Gynaecology and Midwifery of Ahvaz city, randomly double-blinded. They are divided into two groups of intervention (vaginal drug based on traditional medicine) and control (metronidazole vaginal suppository). Patient, researcher, and Statistics Consultant are not aware of any drug content. Medications are delivered to patients according to Block A and B type.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patient Satisfaction, Age 18-50 Years, People with Bacterial Vaginitis and Trichomoniasis؛ Exclusion criteria:Abnormal uterine bleeding, pregnancy and lactation, usage cigaret and alcohol and anticoagulants drug, drug allergy

Intervention groups

"Intervention group": use of traditional medicine (including masoids and zeinans) vaginal suppository 10%, for 7 days, Each day one vaginal suppository (total of 7 vaginal suppositories), (Manufacturer: Center for the Development of Tehran University of Medical Sciences) ; "Control group": use of metronidazole vaginal suppositories 500 mg daily, for 7 days, (total of 7 vaginal suppositories), (Manufacturer: Iran Nazhou)

Main outcome variables

Improvement of the symptoms of bacterial vaginitis and trichomoniasis; Improvement of the recurrence of bacterial vaginitis and trichomoniasis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180217038764N2**
Registration date: **2019-08-24, 1398/06/02**
Registration timing: **retrospective**

Last update: **2019-08-24, 1398/06/02**
Update count: **0**

Registration date

2019-08-24, 1398/06/02

Registrant information

Name
Mojgan Tansaz

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8877 3525

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tansaz_mojgan@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-12, 1397/06/21

Expected recruitment end date
2018-11-15, 1397/08/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of vaginal preparation on the basis of traditional medicine (containing masoids and zeinans) on the recovery and relapse of bacterial vaginitis and trichomoniasis

Public title
The effect of vaginal products on the basis of traditional medicine in Vaginitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patient satisfaction Age 18-50 years Symptoms of bacterial Vaginosis and Trichomoniasis in clinical examinations and tests
Exclusion criteria:
Recent use of anti-parasitic drugs, antibiotics, immunosuppressive drugs and vaginal drugs over the past two weeks Intercourse and using vaginal shower for the last 48 hours Abnormal uterine bleeding Pregnancy and non-Lactation Use of vaginal shower repeatedly Smoking and alcohol consumption and coumarin anticoagulants Multiplicity of sex partners studied Cases of certain diseases such as liver disease, central nervous system diseases,Blood disorders, diabetes, immune deficiency and sexually transmitted diseases having allergy to the medication compounds used in the study.

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
All subjects under study are simple randomized using a random number table, which is created as a set of numbers in a specified order, which is used to read numbers from left to right and drugs with letters A and B have been identified that even numbers for intervention A and the odd numbers for intervention B. The randomization is performed individually for the samples.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to eliminate the bias caused by the knowledge of the patient or the physician and the analyst, a double-blind study is performed. The drugs are marked with letters A and B, and given that the vaginal suppositories containing the traditional medicine and the metronidazole suppository are quite similar, it is natural that the patient and the assessing physician are not aware of the type of drug they receive.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Science,Velenjak,Tehran

City
Tehran

Province
Tehran

Postal code
1516745811

Approval date
2017-10-22, 1396/07/30

Ethics committee reference number
IR.SBMU.RETECH.REC.1396.463

Health conditions studied

1

Description of health condition studied
Bacterial vaginitis and Trichomoniasis

ICD-10 code
N77.1

ICD-10 code description
Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere

Primary outcomes

1

Description
Improvement of symptoms of bacterial vaginitis and trichomoniasis

Timepoint
First follow up 10 days after intervention, Second follow up four weeks after intervention, Third follow up three months after intervention.

Method of measurement
Questionnaire, examination, test

Secondary outcomes

1

Description
Improvement of the recurrence of bacterial vaginitis and trichomoniasis
Timepoint
First follow up 10 days after intervention, Second follow up four weeks after intervention, Third follow up three months after intervention
Method of measurement
Questionnaire, examination, test

Intervention groups

1

Description
"Intervention group": use of traditional medicine (including masoids and zeinans) vaginal suppository 10%, for 7 days, Each day one vaginal suppository (total of 7 vaginal suppositories), (Manufacturer: Center for the Development of Tehran University of Medical Sciences)
Category
Treatment - Drugs

2

Description
"Control group": use of metronidazole vaginal suppositories 500 mg daily, for 7 days, (total of 7 vaginal suppositories), (Manufacturer: Iran Nazhou)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gynecology and Midwifery Center of Ahwaz
Full name of responsible person
Mojgan Tansaz
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1st Floor, Razi Complex, Shahid Dehban St., South Shariati Street
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tansaz_mojgan@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Yaman Street, Shahid Chamran Highway
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mojgan Tansaz
Position
Assistant Professor, Faculty of Traditional Medicine, Shahid Beheshti University
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The questionnaires used and the main outcome information are posted to the subscribers after 3 months of the publication of the results.

When the data will become available and for how long

the access period Starts 3 months after publishing results

To whom data/document is available

Academic Researchers

Under which criteria data/document could be used

Students who are doing thesis in research centers

From where data/document is obtainable

mojgan tansaz tansaz_mojgan@yahoo.com Tel: 02188773525

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

After email reception

Comments