

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of the effect of oak Gall extract vaginal cream and metronidazole vaginal gel in treatment of bacterial vaginosis

Protocol summary

Study aim

The purpose of this study is to compare the effect of vaginal cream extract of oak(jaft) and vaginal metronidazole gel in the treatment of bacterial vaginosis.

Design

In this double-blind study there are 84 women with bacterial vaginosis who have the criteria for entering the study. They are randomly divided into intervention and control groups.

Settings and conduct

This study is a double-blind, randomized controlled clinical trial that will be carried out in women with bacterial vaginosis referring to the women's clinic of Imam Khomeini Hospital, Amiralmomenin Women's Clinic, and Ahvaz Medical Center No. 1 Hospital. Volunteers are randomly assigned to the intervention and control groups using the block randomization method (block of size 4). The researcher and the volunteer will be completely unaware of the content of the vaginal medicine tubes, and pharmaceutical tubes will be filled up by the pharmacist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: at the age of 15-45 years old; being married; diagnosis of bacterial vaginosis with clinical signs and diagnostic tests. Exclusion criteria: Having Candida infection or Trichomoniasis infection with bacterial vaginosis; being pregnant or suspicion of pregnancy; Using IUD; Lactation; Using antibiotics concurrently or during the last two weeks; Using metronidazole for any reason

Intervention groups

Intervention group: oak extract vaginal cream. Control group: metronidazole vaginal gel

Main outcome variables

Cure of bacterial vaginosis; vaginosis clinical and laboratory signs alleviation; reduction of target infectious factors including pathogenic bacteria.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180122038477N1**

Registration date: **2018-07-27, 1397/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-27, 1397/05/05**

Update count: **0**

Registration date

2018-07-27, 1397/05/05

Registrant information

Name

Elham Afzali

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-14, 1397/04/23

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oak Gall extract vaginal cream and metronidazole vaginal gel in treatment of bacterial vaginosis

Public title

oak Gall extract vaginal cream and metronidazole vaginal gel in treatment of bacterial vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 15 to 45 years Being married Diagnosis of bacterial vaginosis with clinical symptoms and diagnostic tests

Exclusion criteria:

Having a candida infection or trichomoniasis infection associated with bacterial vaginosis Pregnancy and Doubt to It Use of IUD Use antibiotic simultaneously or over the past two weeks Lactation Taking metronidazole for any reason at the same time

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done a non-probabilistic manner. The method of assigning oak extract Cream (jaft) and metronidazole gel to patients is randomized and randomized blocks with block size 4 (using a random permutation table). A randomized list provide by statistician. In this study, oak extract Cream (jaft) and metronidazole gel will be placed in the closed envelopes according to the randomized list and different codes by the person outside the study then assigned to any patient that enter the study. oak extract Cream (jaft) and metronidazole gel are identical in appearance, packaging, color. The nature of the oak extract Cream (jaft) and metronidazole gel are apparent after the analysis of the result.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, Researcher and participants will be unaware of the type of treatment they receive (oak extract Cream (jaft) or metronidazole gel) and pharmacist will fill the tubes. For the purpose of blinding, oak extract Cream (jaft) and metronidazole gel tubes will be placed in closed envelopes according to the randomized list and different codes will be assigned to any patient that enters the study by a person outside the

study. Oak extract Cream (jaft) or metronidazole gel tubes are identical in appearance, packaging and color. The nature of oak extract Cream (jaft) and metronidazole gel will be revealed after the analysis and patients will be reminded that their placement in each of the groups will be random.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences and Health Services

Street address

Ahvaz Jundishapur University of Medical Sciences and Health Services, Golestan BLV, Ahvaz

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Postal code

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Approval date

2018-01-13, 1396/10/23

Ethics committee reference number

IR.AJUMS.REC.1396.859

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Health conditions studied

1

Description of health condition studied

Bacterial vaginosis

ICD-10 code

N76.0

ICD-10 code description

Acute vaginitis

Primary outcomes

1

Description

Bacterial vaginosis cure

Timepoint

4 to 7 days after treatment

Method of measurement

Based on the criteria of Amsell (Evaluation of vaginal discharge in terms of odor, color and presence of key cells with the emphasis on emphasis)

Secondary outcomes

1

Description

Vaginal discharge

Timepoint

Before treatment and 4 to 7 days after treatment

Method of measurement

Observation

2

Description

The acidity of vagina

Timepoint

Before treatment and 4 to 7 days after treatment

Method of measurement

PH strip

3

Description

Whiff test

Timepoint

Before treatment and 4 to 7 days after treatment

Method of measurement

Potassium hydroxide solution 10%

4

Description

clue cells

Timepoint

Before treatment and 4 to 7 days after treatment.

Method of measurement

Evaluation of clue cells on the wet lam

Intervention groups

1

Description

Intervention group: oak extract (Jaft) 2.5% Vaginal cream, 5 mg per night for 5 nights

Category

Treatment - Drugs

2

Description

Control group: metronidazole 75% gel, 5 mg every night for 5 nights.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz East Health Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Alham afzali

Position

Masters Student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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

No - There is not 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