

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of Quercus, Punicagranatum, Malvasylvestris, Cinnamomumverumherbal capsules on the treatment of fungal and bacterial infections and wound healing and vaginal inflammations

Protocol summary

Study aim

Investigating the effect of Quercus, Punicagranatum, Malvasylvestris, Cinnamomumverum herbal capsules on the treatment of fungal, bacterial infections and vaginal inflammations

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, on 100 patients. which random number table was used for randomization. Vaginal infections before and after the intervention will be investigated by clinical examination by a gynecologist and pap smear test. Pap smear will be taken before the intervention and 4 weeks after the treatment. The intervention group was prescribed herbal capsules of Quercus, Punicagranatum, Malvasylvestris, Cinnamomumverum (one vaginally every night) produced by Daru Darman Mahsan Nafis with limited responsibility by registration number 4831, and the control group was prescribed only placebo.

Settings and conduct

Clinical trial with control group, with parallel groups, single-blind, randomized, on 100 patients. which random number table was used for randomization. Vaginal infections before and after the intervention will be investigated by clinical examination by a gynecologist and pap smear test. Pap smear will be taken before the intervention and 4 weeks after the treatment. The intervention group was prescribed herbal capsules of Quercus, Punicagranatum, Malvasylvestris, Cinnamomumverum (one vaginally every night) produced by Daru Darman Mahsan Nafis with limited responsibility by registration number 4831, and the control group was prescribed only placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: samples were diagnosed with vaginitis by a gynecologist, age group 20-50 years, being married. Do not enter: Allergy to herbal medicines

Intervention groups

There are 100 married women who refer to women's specialist clinic due to vaginal infections.

Main outcome variables

Fungal infections, bacterial infections and inflammation

General information

Reason for update

Please, the name of the company that provides the drug to the researcher should be mentioned in the summary of the trial placed on the site

Acronym

IRCT registration information

IRCT registration number: **IRCT20131110015349N4**

Registration date: **2023-06-11, 1402/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-27, 1402/04/06**

Update count: **1**

Registration date

2023-06-11, 1402/03/21

Registrant information

Name

Maryam Allahdadian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1668 7140

Email address

allahdadian@iaufala.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Quercus, Punicagranatum, Malvasylvestris, Cinnamomumverumherbal capsules on the treatment of fungal and bacterial infections and wound healing and vaginal inflammations

Public title

Investigating the effect of Quercus, Punicagranatum, Malvasylvestris, Cinnamomumverumherbal capsules on the treatment of vaginal infection

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

.Willingness to participate in the study They have a vaginal infection

Exclusion criteria:

Have a history of diseases that weaken the immune system, diabetes, or metabolic diseases They are taking chemical drugs for vaginitis. Unwilling patients will be excluded from the study

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization model was used, using a lottery. In this way, 100 people who came to the office and met the entry criteria were assigned a number, then all the numbers were thrown into a ball and one person was selected by lottery. The intervention group and one person was assigned to the control group

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants do not know whether they are in the drug or placebo group. The herbal medicine is powdered and poured into a dark capsule cover, so that the contents cannot be seen. Placebo capsules are filled with dark colored flour. The participant does not know whether the capsule they are receiving is placebo or treatment.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of Islamic Azad University- Najafaba Branch

Street address

University Boulevar, Islamic Azad University, Najaf Abad branch

City

Najafabad

Province

Isfahan

Postal code

851413131

Approval date

2022-09-29, 1401/07/07

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1401.121

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

Inflammatory disease of cervix uteri

ICD-10 code

N72

ICD-10 code description

Inflammatory disease of cervix uteri

2**Description of health condition studied**

Candidiasis of vulva and vagina

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

3**Description of health condition studied**

Vaginitis

ICD-10 code

N76.0

ICD-10 code description

Acute vaginitis

Primary outcomes

1

Description

Inflammation

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Pap smear result

2

Description

Fungal infections

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Pap smear result

3

Description

Bacterial infection

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Pap smear result

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, "the effect of Quercus, Punicagranatum, Malvasylvestris, Cinnamomumverumherbal capsules from Daru Darman Mahsan Nafis with limited responsibility by registration number 4831 on the dependent variables of fungal and bacterial infections and vaginal inflammations in women is investigated. On the other hand, the study will be conducted in case and control groups, and the allocation of control and case groups was random. This clinical trial, single-blind, placebo-controlled, and two-group before and after, will be conducted on 100 people with vaginal infections who will visit the women's office in Isfahan during 2023.

Category

Treatment - Drugs

2

Description

Control group: In the control group, a pap smear was taken first, and then a placebo was given to the patient, and after one month the results of the pap smear were

checked.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecologist's office

Full name of responsible person

Maryam Allahdadian

Street address

Basij Boulevard, Islamic Azad University, Falavarjan branch

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Isfahan

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Isfahan

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8451731167

Phone

+98 31 3742 0134

Fax

Email

maryamallahdadian@yahoo.com

Web page address

<https://falavarjan.iau.ir/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Allahdadian

Street address

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Grant name

Grant code / Reference number

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

No

Title of funding source

Daru Darman Mahsan Nafis with limited responsibility by registration number 4831

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

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

Islamic Azad University

Full name of responsible person

Maryam Allahdadian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Web page address<https://falavarjan.iau.ir/fa>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Maryam Allahdadian

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Web page address<https://falavarjan.iau.ir/fa>**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Maryam Allahdadian

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Email

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Web page address<https://falavarjan.iau.ir/fa>**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

confidentiality

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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