

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Exploring The Combined Therapeutic Effects Of Ayurvedic Herbal Formulation Against Leucorre

Protocol summary

Study aim

The study evaluated the efficacy of an Ayurvedic medicine regimen in managing symptoms of vaginal discomfort among women

Design

Pragmatic, community based, parallel group, single blinded, randomized controlled trial. Total 65 patients will be enrolled. Patients who met our inclusion criteria will be randomized into three groups.

Settings and conduct

At Noreen Nishat Welfare Hospital ,Khanewal ,Pakistan after approval for the study design granted by the Review Board and the Ethical Committee of Muhammad Institute of Medical and Allied Sciences, Multan, Pakistan.

Participants/Inclusion and exclusion criteria

Females of aged 16-55 years, with symptoms of abnormal vaginal discharge, excessive vaginal irritation, and itching, will be chosen for the study. Strict exclusions included pregnant women (due to altered vaginal flora and fetal safety concerns), those with prolapsed uterus (potential impact on symptoms), history of malignancy (to avoid treatment-related complications), severe illnesses (to maintain study integrity), and individuals with known allergies (to prevent confounding reactions)

Intervention groups

Participants will be assigned to three groups: Positive Control (G1) will receive oral Metro gel (metronidazole, 5 grams/day for 5 days), Negative Control (G2) will receive no allopathic medicine (distilled water), and Experimental Group (G3) will receive daily ayurvedic medicine (10 grams/day for 30 days)

Main outcome variables

Primary symptoms will be assessed included excessive vaginal discharge, itching, swelling, redness, and unpleasant odor. Secondary symptoms evaluated will be back pain, constipation, loss of appetite, painful intercourse, and general well-being.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230202057310N8**

Registration date: **2024-08-20, 1403/05/30**

Registration timing: **retrospective**

Last update: **2024-08-20, 1403/05/30**

Update count: **0**

Registration date

2024-08-20, 1403/05/30

Registrant information

Name

Imran Ahmad Khan

Name of organization / entity

Muhammad Nawaz Shareef University of Agriculture, Multan

Country

Pakistan

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-30, 1403/04/10

Expected recruitment end date

2024-08-19, 1403/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Exploring The Combined Therapeutic Effects Of Ayuvedic Herbal Formulation Against Leucorre

Public title

Therapeutic Effects Of Ayuvedic Herbal Formulation Against Leucorre

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged 16-55 year Symptoms of abnormal vaginal discharge Excessive vaginal irritation Vaginal itching Females

Exclusion criteria:

Pregnant women (due to altered vaginal flora and fetal safety concerns) Those with prolapsed uterus (potential impact on symptoms), History of malignancy (to avoid treatment-related complications) Severe illnesses (to maintain study integrity) Individuals with known allergies (to prevent confounding reactions).

Age

From **16 years** old to **55 years** old

Gender

Female

Phase

1

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

This randomization will be done by computer-generated numbers to ensure fairness. Medications will be given in numbered white boxes, each with a unique medication number. The treatment codes will be kept by the principal investigator.

Blinding (investigator's opinion)

Double blinded

Blinding description

Statistical analyser and outcome assessor will be kept blind so that the result obtained will be without biasness.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

The Institutional Ethical Committee of Muhammad Institute of Medical and Allied Sciences

Street address

Bosan Road

City

Multan

Postal code

66000

Approval date

2024-05-01, 1403/02/12

Ethics committee reference number

2024/IRB/3/MIMAS/05

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

Leucorre:Diseases of the genitourinary system

ICD-10 code

N00-N99

ICD-10 code description

Leucorre:Diseases of the genitourinary system

Primary outcomes**1****Description**

Excessive vaginal discharge

Timepoint

1 month

Method of measurement

The whiff test detected bacterial vaginosis through the presence of a fishy odor, and Gram staining identified bacterial species present in vaginal discharge

2**Description**

Vaginal discharge examination

Timepoint

1 month

Method of measurement

The pH test measured vaginal acidity (normal range 3.8-4.5), the whiff test detected bacterial vaginosis through the presence of a fishy odor, and Gram staining identified bacterial species present in vaginal discharge

Secondary outcomes**1****Description**

Back pain

Timepoint

1 month

Method of measurement

Visual Analog Scale

2

Description

Constipation, loss of appetite, painful intercourse and general well-being.

Timepoint

1 month

Method of measurement

By asking questions and discussing with patients

Intervention groups

1

Description

Control group: Positive Control (G1) received oral Metro gel (metronidazole, 5 grams/day for 5 days)

Category

Treatment - Drugs

2

Description

Control group: Negative Control (G2) received no allopathic medicine (distilled water)

Category

Treatment - Drugs

3

Description

Intervention group: Experimental Group (G3) received daily ayurvedic medicine (10 grams/day for 30 days)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Noreen Nishat Welfare Hospital, Khanewal, Pakistan

Full name of responsible person

Mashhud-UI-Hasan Abid

Street address

Khanewal

City

Khanewal

Postal code

58150

Phone

+92 301 7412473

Email

mashhud.biochemist@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Muhammad Institute of Medical and Allied Sciences
Multan

Full name of responsible person

Mashhud-UI-Hasan Abid

Street address

Bosan Road

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Grant name

Student fund

Grant code / Reference number

MIMAS/06/05/Rabish

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

Yes

Title of funding source

Muhammad Institute of Medical and Allied Sciences
Multan

Proportion provided by this source

70

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Muhammad Institute of Medical and Allied Sciences,
Multan

Full name of responsible person

Mashhud-UI-Hasan Abid

Position

Lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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HBL street, Sbzazar metro station, Bosan road,
Multan, Pakistan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Muhammad Nawaz Sharif University of Agriculture,
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Lecturer

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Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Position

Final year student BS (hons.)

Latest degree

Bachelor

Other areas of specialty/work

Biochemistry

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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

N/A

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available