# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Exploring The Combined Therapeutic Effects Of Ayuvedic 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 recieve 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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**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-Ul-Hasan Abid
**Street address**
Khanewal
**City**
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**Postal code**
58150
**Phone**
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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**
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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-Ul-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

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Medical Pharmacy

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## Person responsible for updating data

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Rabish Rafique

**Position**
Final year student BS (hons.)

**Latest degree**
Bachelor

**Other areas of specialty/work**
Biochemistry

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

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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