

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Evaluation of the Anti-Cholelithiasis Activity of Vinegar-Soaked Ficus carica Fruit in Adults: A Randomized Controlled Trial

#### Protocol summary

##### Study aim

This randomized controlled trial aims to evaluate the anti-cholelithiasis activity of vinegar-soaked Ficus carica fruit in adults diagnosed with cholelithiasis.

##### Design

Pragmatic, community based, parallel group, single blinded, randomised controlled trial. Total 50 patients will be enrolled. Patients who met our inclusion criteria will be randomised into two groups. Treatment group-A and control group-B

##### Settings and conduct

At Noreen Nishat Welfare Hospital ,Khanewal ,Pakistan (ref no: 1015) 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

Inclusion criteria: Participants in the study will be included who will be adults aged 18 to 50 years diagnosed with cholelithiasis, confirmed by a radiologist pediatrician through ultrasound testing and of both genders. Exclusion criteria: The exclusion criteria included individuals with major systemic diseases, prior gallbladder surgery, gallstone medications, or pregnancy and lactating mothers

##### Intervention groups

Participants in the the control group-A will be given ursodiol 600 mg per day as the standard drug, and treatment group-B participants will be given VSFCF orally at a standard dose of 1g/kg/day for 3 months to assess the treatment's effects. Both groups will be adhere to the same schedule and duration of administration for a comparative analysis of outcomes.

##### Main outcome variables

In the study, the primary outcome focus will be on evaluating changes in gallstone size that will be measured at the beginning and after 3 months of intervention. Additionally, secondary outcomes included analyzing the composition of gallstones to understand

any structural changes.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230202057310N7**

Registration date: **2024-06-13, 1403/03/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-06-13, 1403/03/24**

Update count: **0**

##### Registration date

2024-06-13, 1403/03/24

##### Registrant information

##### Name

Imran Ahmad Khan

##### Name of organization / entity

Muhammad Nawaz Shareef University of Agriculture, Multan

##### Country

Pakistan

##### Phone

+92 333 6120602

##### Email address

imran.ahmad@mnsuam.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-03-10, 1402/12/20

##### Expected recruitment end date

2024-06-30, 1403/04/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the Anti-Cholelithiasis Activity of Vinegar-Soaked Ficus carica Fruit in Adults: A Randomized Controlled Trial

**Public title**  
Anti-Cholelithiasis Activity of Vinegar-Soaked Ficus carica Fruit in Adults

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Participants in the study were adults aged 18 to 50 years  
Both male and female Participants diagnosed with cholelithiasis  
**Exclusion criteria:**  
Individuals with major systemic diseases Individuals with prior gallbladder surgery Individuals taking gallstone medications Pregnancy ladies Lactating mothers

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

**Gender**  
Both

**Phase**  
1-2

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In the study, eligible adults will be randomly allocated to therapeutic groups at a 1 : 1 ratio using the permuted randomization method.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Single blinded study. Statistical analyser 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**  
HBL Street near Sabsazar Metro Station

**City**  
Multan

**Postal code**  
66000

**Approval date**  
2024-03-15, 1402/12/25

**Ethics committee reference number**  
MIMAS/05/IAK Durrani

## Health conditions studied

1

**Description of health condition studied**  
Cholelithiasis

**ICD-10 code**  
K80

**ICD-10 code description**  
Cholelithiasis

## Primary outcomes

1

**Description**  
Evaluating changes in gallstone size

**Timepoint**  
3 months

**Method of measurement**  
Ultrasound or imaging techniques

## Secondary outcomes

1

**Description**  
Analyzing the composition of gallstones to understand any structural changes, assessing symptoms related to gallstones such as pain, bloating, and digestive discomfort to gauge symptomatic improvement, and monitoring safety parameters like adverse events

**Timepoint**  
3 months

**Method of measurement**  
By finding cholesterol, bilirubin, and calcium values in body and by liver function tests

## Intervention groups

1

**Description**  
Control group-A: The participants of control group-A will be given ursodiol 600 mg per day as the standard drug, ensuring that any observed results in the treatment group are due to the intervention itself rather than the effects of ursodiol.

**Category**

Treatment - Drugs

**2****Description**

Intervention group-B: Participants of treatment group-B will be given vinegar-soaked Ficus carica fruit (VSFCF) orally at a standard dose of 1g/kg/day for 3 months to assess the treatment's effects.

**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**

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**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

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HLB street, Sbzazar metro station, Bosan road,  
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**Grant name**

Student fund

**Grant code / Reference number**

MIMAS/06/05/Malaika

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

No

**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**

Master

**Other areas of specialty/work**

Biochemistry

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

Muhammad Nawaz Sharif University of Agriculture,  
Multan, Pakistan

**Full name of responsible person**

Imran Ahmad Khan

**Position**

Lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Muhammad Institute of Medical and Allied Sciences,  
Multan  
**Full name of responsible person**  
Malaika Bukhari  
**Position**  
Final year student BS (hons.) Biochemistry  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Biochemistry  
**Street address**  
HBL street, Sbzazar metro station, Bosan road,  
Multan, Pakistan  
**City**  
Multan  
**Province**  
Punjab

## 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

Undecided - It is not yet known if there will be 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