Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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. Excluison 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

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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-Ul-Hasan Abid
Street address
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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-Ul-Hasan Abid
Street address
HBL street, Sbzazar metro station, Bosan road, Multan, Pakistan
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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-Ul-Hasan Abid
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Biochemistry
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Final year student BS (hons.) Biochemistry

Latest degree
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Other areas of specialty/work
Biochemistry

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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
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