Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Hepatoprotective Effects of Jasminum sambac on Individuals With Non alcoholic Fatty Liver Disease's Metabolic Profiles

Protocol summary

Study aim
To examine the effects of J. sambac consumption in combination with a conventional diet on glycemic indices, lipid profiles, inflammatory activity, platelet aggregation and measures of oxidative stress in NAFLD patients.

Design
Pragmatic, community bases, parallel group, double blinded, randomised control trial. 90 patients will be enrolled into 3 groups. Study will be done form March-May 2023

Settings and conduct
At Muhammad's physical therapy clinic and rehabilitation center, Multan, Pakistan, 90 suitable persons who had just received a fresh diagnosis of NAFLD (38 men and 52 women) were gathered from outpatient visits

Participants/Inclusion and exclusion criteria
Participants in the study were to be 23 to 77 years old, have a body mass index >25 kg/m2, and have diagnosed NAFLD as determined by an ultrasound examination. The following were the exclusion criteria:following a weight reduction diet in the three months earlier, modifying dosage of anti-diabetic, anti-hyperlipidemic, and anti-hypertensive drugs, ingesting just under 70percent of the J. sambacsalad,nicotine, using other drugs, and a past stroke, cardiomyopathy, diabetes, any form of the severe retinal disorder, stomach ulcers, kidney stones, or any additional liver, kidney, lung, or heart disease, among other underlying illness

Intervention groups
Before lunch, the 1st group (intervention group) was instructed to eat the conventional diet combined with 200 mg/kg bw/day(12) of J.sambac in the form of salad, while the 2nd group (positive control) received the silymarin with 100mg/kg bw 2 times a day and the 3rd group (negative control) just got the conventional diet. The recommended diet, which included 20% protein, 55% carbohydrate, and 30% fat, supplied around 1500 kcal/day

Main outcome variables
Glycemic indices, lipid profiles, inflammatory activity, platelet aggregation and measures of oxidative stress

General information

Reason for update
Mistakenly some data have been put which needs correction. Please evaluate and accept

Acronym

IRCT registration information
IRCT registration number: **IRCT20230424057987N1**
Registration date: **2023-04-29, 1402/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-10, 1402/02/20**
Update count: **1**

Registration date
2023-04-29, 1402/02/09

Registrant information

Name
Imran Ahmad Khan
Name of organization / entity
Muhammad Nawaz Shareef University of Agriculture, Multan, Pakistan.
Country
Pakistan
Phone
+92 333 6120602
Email address
imranahmadkhandurrani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-05, 1401/12/14

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Hepatoprotective Effects of Jasminum sambac on Individuals With Non alcoholic Fatty Liver Disease's Metabolic Profiles

Public title

Effects of Jasminum sambac on Individuals With Non alcoholic Fatty Liver Disease's Metabolic Profiles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants in the study were to be 23 to 77 years old Body mass index >25 kg/m2 Participants diagnosed with NAFLD as determined by an ultrasound examination

Exclusion criteria:

Following a weight reduction diet in the three months earlier Anti-diabetic, anti-hyperlipidemic, and anti-hypertensive drugs Past stroke Cardiomyopathy Diabetes Retinal disorder Stomach ulcers Kidney stones Using other drugs

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Double blinded study i-e randomization of participants in groups by lottery method and statistical analysis without biasness.

Blinding (investigator's opinion)

Double blinded

Blinding description

Investigator and data analyser will be kept blind to avoid any biasness as this is a double blinded study

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

2023-02-05, 1401/11/16

Ethics committee reference number

MIMAS/06/26/I.A.K.DURRANI

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Nonalcoholic fatty liver disease

Primary outcomes

1

Description

Fasting blood sugar (FBS)

Timepoint

3 months

Method of measurement

Venous blood samples willbe taken at the start and completion of the trial

2

Description

Triglycerides (TG)

Timepoint

3 months

Method of measurement

Venous blood samples will be taken at the start and completion of the trial and then evaluated using an enzymatic colorimetric assay utilizing commercial kits (Pars Azmoon).

3

Description

Total cholesterol (TC), LDL cholesterol (LDL-C), and high-density lipoprotein cholesterol (HDL-C)

Timepoint

3 months

Method of measurement

Venous blood samples will be taken at the start and completion of the trial and then evaluated using an enzymatic colorimetric assay utilizing commercial kits (Pars Azmoon). After apolipoprotein B-containing lipoproteins were precipitated using chloride magnesium and dextran sulphate as part of the oxidase cholesterol technique, serum HDL and LDL cholesterol levels were measured.

4

Description
ALT(alanine transaminase), AST (aspartate aminotransferase), ALP (alkaline phosphatase) , LDH (lactate dehydrogenase)
Timepoint
3 months
Method of measurement
Venous blood samples will be taken at the start and completion of the trial

5

Description
Total antioxidant capacity
Timepoint
3 months
Method of measurement
Assessed by using 2,2-diphenyl-1-picrylhydrazyl (DPPH)

6

Description
Platelet aggregation and platelet activation.
Timepoint
3 months
Method of measurement
Platelet aggregation was evaluated using impedance aggregometry, and platelet activation was assessed using flow cytometry.

7

Description
Inflammation
Timepoint
3 months
Method of measurement
Inflammation measured by check the CRP level.

Secondary outcomes

1

Description
Systolic (SBP) and diastolic blood pressure(DBP)
Timepoint
3 months
Method of measurement
Sphygmomanometer

Intervention groups

1

Description
Intervention group: 1st group (interventional group) was instructed to eat the conventional diet combined with 200 mg/kg bw/day of J.sambac in the form of salad,
Category
Treatment - Other

2

Description
Control group: 2nd group (positive control) received the silymarin with 100mg/kg bw 2 times a day
Category
Treatment - Other

3

Description
Control group: 3rd group (negative control) just got the conventional diet. The recommended diet, which included 20% protein, 55% carbohydrate, and 30% fat, supplied around 1500 kcal/day
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Muhammad's physical therapy clinic and rehabilitation center, Multan, Pakistan
Full name of responsible person
Imran Ahmad Khan
Street address
HBL Street near Sabsazar Metro Station
City
Multan
Postal code
66000
Phone
+92 333 6120602
Email
imranahmadkhandurrani@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ali –Ul- Murtaza Department of Rehabilitation Science, MIMAS
Full name of responsible person
Imran Ahmad Khan
Street address
Hbl street sabsazar metro station

City
Multan
Postal code
66000
Phone
+92 333 6120602
Email
imranahmadkhandurrani@gmail.com

Grant name
Student fund

Grant code / Reference number
26082023

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

Title of funding source
Ali –Ul- Murtaza Department of Rehabilitation Science, MIMAS

Proportion provided by this source
100

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
Ali –Ul- Murtaza Department of Rehabilitation Science, MIMAS
Full name of responsible person
Hifza Arif
Position
Lecturer
Latest degree
Medical doctor
Other areas of specialty/work
Physiotherapy
Street address
Hbl street sabsazar metro station
City
Multan
Province
Punjab
Postal code
66000
Phone
+92 309 7697428
Email
hifzaa630@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Department of Pharmacology and Physiology, MNS University of Agriculture, Multan, Pakistan.
Full name of responsible person
Imran Ahmad Khan
Position
Coordinator
Latest degree
Ph.D.
Other areas of specialty/work
Cardiovascular Pharmacology
Street address
Agriculture Complex, Old Shuja Abad Rd, Multan, Punjab
City
Multan
Province
Punjab
Postal code
66000
Phone
+92 333 6120602
Email
imran.ahmad@mnsuam.edu.pk

Person responsible for updating data

Contact

Name of organization / entity
Ali –Ul- Murtaza Department of Rehabilitation Science,MIMAS
Full name of responsible person
Hifza Arif
Position
Lecturer
Latest degree
Medical doctor
Other areas of specialty/work
Physiotherapy
Street address
Hbl street sabsazar metro station
City
Multan
Province
Punjab
Postal code
66000
Phone
+92 309 7697428
Email
hifzaa630@gmail.com

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
No - There is not 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