

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. sambac* salad, 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 will be 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

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Multan

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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

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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 -UI- 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 -UI- Murtaza Department of Rehabilitation Science, MIMAS
Full name of responsible person
Hifza Arif
Position
Lecturer
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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
Hifza Arif
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Other areas of specialty/work
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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
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