

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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/m<sup>2</sup>, 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

###### **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**  
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**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 -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  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Hbl street sabsazar metro station  
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66000  
**Phone**  
+92 309 7697428  
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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**  
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## Person responsible for updating data

**Contact**  
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Ali -UI- Murtaza Department of Rehabilitation Science, MIMAS  
**Full name of responsible person**  
Hifza Arif  
**Position**  
Lecturer  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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**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