

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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 from 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 70 percent 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**  
+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 -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

**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 -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

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**Phone**  
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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