

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Synergistic Effect of Berberis Aristata and Metformin in Diabetic Patients- A Randomized Controlled Trial

#### Protocol summary

##### Study aim

This study aims to find out synergistic effect Berberis aristata and metformin in lowering blood glucose level in diabetic patients. Diabetes mellitus is a chronic metabolic disorder characterized by high blood glucose levels

##### Design

Lottery method, community bases, parallel group, double blinded, randomized control trial.

##### Settings and conduct

Study will be conducted at Muhammad Institute of Medical and Allied Sciences Multan after approval from Institutional ethical committee.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age group of 25-70 years Both Genders (Male, Female) Hypertensive patients Married and unmarried Educated and uneducated Diabetic patients  
Exclusion criteria: Any type of mental disability Lactating females Having any type of physical disability History of chest pain, bronchitis, asthma, angina, MI Chronic illness related to cardiorespiratory ailments Any type of major surgery • Pregnant females

##### Intervention groups

Patients will be recruited by using the lottery method into three groups. Informed consent will be taken from patient. Group A will be treated with Berberis aristata (550 mg twice a day) orally. Group B will be given metformin orally (500 mg). Group C will be given both Berberis aristata and metformin (550/250 mg once). The treatment regimen will be 6 weeks. Blood glucose, blood pressure, blood cholesterol, respiration rate, heart rate, ketone bodies, HbA1c, DDS score and oxygen saturation of all the patients with diabetes type-2 at baseline and after 6 weeks.

##### Main outcome variables

Cardiometabolic and cardiorespiratory parameters including Blood glucose, blood pressure, blood cholesterol, respiration rate, heart rate, ketone bodies, HbA1c, DDS score and oxygen saturation

#### General information

##### Reason for update

Slight modifications

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230202057310N3**

Registration date: **2023-09-07, 1402/06/16**

Registration timing: **prospective**

Last update: **2024-08-20, 1403/05/30**

Update count: **1**

##### Registration date

2023-09-07, 1402/06/16

##### Registrant information

##### Name

Imran Ahmad Khan

##### Name of organization / entity

Muhammad Nawaz Shareef University of Agriculture, Multan

##### Country

Pakistan

##### Phone

+92 333 6120602

##### Email address

imran.ahmad@mnsuam.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-10, 1402/06/19

##### Expected recruitment end date

2024-01-06, 1402/10/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Synergistic Effect of Berberis Aristata and Metformin in Diabetic Patients-A Randomized Controlled Trial

### Public title

Berberis Aristata and Metformin in Diabetic Patients

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age group of 25-70 years Both Genders (Male, Female)  
Married and unmarried Educated and uneducated  
Diabetic patients

#### Exclusion criteria:

Any type of mental disability Lactating females Having any type of physical disability History of chest pain bronchitis Any type of major surgery Pregnant females Asthma Angina MI Chronic illness related to cardiorespiratory ailments

### Age

From **25 years** old to **70 years** old

### Gender

Both

### Phase

1-2

### Groups that have been masked

- Investigator
- Data analyser

### Sample size

Target sample size: **295**

### Randomization (investigator's opinion)

Randomized

### Randomization description

We used sealed envelopes for lottery method and randomization of participants was done. Randomization of participants in groups by lottery method Simple randomization.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Double blinded study was done by keeping blind i.e the physiotherapist as Investigator and data analyser to avoid biasness and to get the authentic results

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Muhammad Institute of Medical and Allied Sciences  
Multan

#### Street address

HBL Street, Bosan Road Multan.

#### City

Multan

#### Postal code

66000

#### Approval date

2023-08-10, 1402/05/19

#### Ethics committee reference number

MIMAS/08/27/IAK.DURRANI

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes Mellitus

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

Glucose level in diabetic patients

#### Timepoint

6 weeks

#### Method of measurement

Blood glucose level by glucometer

### 2

#### Description

Cholesterol level

#### Timepoint

6 weeks

#### Method of measurement

Lipid profile meter

### 3

#### Description

HbA1C

#### Timepoint

6 weeks

#### Method of measurement

Blood sampling

## Secondary outcomes

### 1

#### Description

Cardiorespiratory parameters

#### Timepoint

6 weeks

#### Method of measurement

## Intervention groups

### 1

#### Description

Intervention group: Group A will be treated with Berberis aristata (550 mg twice a day) orally. The treatment regimen will be 6 weeks. Blood glucose, blood pressure, blood cholesterol, respiration rate, heart rate, ketone bodies, HbA1c, DDS score and oxygen saturation of all the patients with diabetes type-2 at baseline and after 6 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Group B will be given metformin orally (500 mg). The treatment regimen will be 6 weeks. Blood glucose, blood pressure, blood cholesterol, respiration rate, heart rate, ketone bodies, HbA1c, DDS score and oxygen saturation of all the patients with diabetes type-2 at baseline and after 6 weeks

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: Group C will be given both Berberis aristata and metformin (550/250 mg once). The treatment regimen will be 6 weeks. Blood glucose, blood pressure, blood cholesterol, respiration rate, heart rate, ketone bodies, HbA1c, DDS score and oxygen saturation of all the patients with diabetes type-2 at baseline and after 6 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Muhammad Institute of Medical and Allied Sciences  
Multan

##### Full name of responsible person

Maliha Khalid Khan

##### Street address

Hbl street sabsazar metro station

##### City

Multan

##### Postal code

66000

##### Phone

+92 312 6827130

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Muhammad Institute of Medical and Allied Sciences,  
Multan

##### Full name of responsible person

Imran Ahmad Khan

##### Street address

Hbl street sabsazar metro station

##### City

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##### Postal code

66000

##### Phone

+92 333 6120602

##### Email

imranahmadkhandurrani@gmail.com

#### Grant name

Student fund

#### Grant code / Reference number

27082023

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

Yes

#### 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

Maliha Khalid Khan

##### Position

Demonstrator

##### 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**

+92 312 6827130

**Email**

malihatareen1997@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**Department of Pharmacology and Physiology, MNSUA  
Multan.**Full name of responsible person**

Imran Ahmad Khan

**Position**

Lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Old Shuja Bad Road Multan

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Multan

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**Phone**

+92 333 6120602

**Email**

imran.ahmad@mnsuam.edu.pk

**Person responsible for updating data****Contact****Name of organization / entity**Muhammad Institute of Medical and Allied Sciences,  
Multan**Full name of responsible person**

Tooba Hareem

**Position**

Final year student of DPT

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physiotherapy

**Street address**

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**City**

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**Province**

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**Postal code**

66000

**Phone**

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**Email**

toobahareem1@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**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