

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

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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

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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

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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

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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**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