Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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+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 envelops for lotterty 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 ro 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

Pulse oximeter, Manometer for blood pressure monitoring

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
malihatareen1997@gmail.com

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
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Multan
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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
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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 yeasr 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