

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

To compare the safety and efficacy of Dapagliflozin and Glimepiride as add-on to Metformin in patients with type 2 diabetes.

Protocol summary

Study aim

To identify the effective treatment option between dapagliflozin-metformin and glimepiride-metformin combination in patients with type 2 diabetes who were inadequately controlled with metformin monotherapy.

Design

This was a randomized, parallel arm controlled trial (Phase-4) without blinding and allocation concealment. Using a sample size of 200 participants. Randomisation was performed on computer software (excel) after which the participants were divided into two interventional groups i.e. Group 1 (Glimepiride + Metformin therapy) and Group 2 (Dapagliflozin + Metformin therapy). The study duration was 12 weeks, the study started in October 2019 till April 2020. Patient enrollments was done from October 2019 till February 2020.

Settings and conduct

It was conducted for 12 weeks at the National Medical center, Karachi, Pakistan. The patients were divided into 2 treatment groups; group 1 was given glimepiride-metformin combination, while group 2 was given dapagliflozin-metformin combination

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetics aged 45-55 years with impaired FPG and HbA1c using metformin monotherapy.
Exclusion criteria: Comorbidities (Hypertension), Cardiovascular disease, cancers, taking antidiabetic therapy other than metformin and unwillingness to participate in the study

Intervention groups

Intervention group 1: This group will include patients, who will receive Glimepiride (4mg) once daily, with Metformin (500 mg) orally thrice daily for 12 weeks.
Intervention group 2: This group will include patients, who will be given with Tab Dapagliflozin (10mg) once daily, with Metformin (500mg) orally thrice daily for 12 weeks.

Main outcome variables

Hemoglobin A1c (HbA1c); fasting plasma glucose (FPG).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220408054450N1**

Registration date: **2022-09-11, 1401/06/20**

Registration timing: **retrospective**

Last update: **2022-09-11, 1401/06/20**

Update count: **0**

Registration date

2022-09-11, 1401/06/20

Registrant information

Name

Muhammad Sharib Syed

Name of organization / entity

Metrics Research Pvt Ltd

Country

Pakistan

Phone

+92 21 37224982

Email address

regulatory@mrcro.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-15, 1398/07/23

Expected recruitment end date

2020-02-15, 1398/11/26

Actual recruitment start date

2019-10-15, 1398/07/23

Actual recruitment end date

2020-02-01, 1398/11/12

Trial completion date

2020-04-14, 1399/01/26

Scientific title

To compare the safety and efficacy of Dapagliflozin and Glimepiride as add-on to Metformin in patients with type 2 diabetes.

Public title

Comparing Dapagliflozin and Glimepiride in treating patients with type 2 Diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

normal baseline levels of LFT, RFT, lipid profile, and white blood cell count (WBC). The fasting plasma glucose (FBG) levels of all recruited participants to be ≥ 126 mg/dL hemoglobin A1c levels to be >7 -10% 1500 mg/day metformin monotherapy for last 3 to 6 months. Age of 45-55 years old Either gender

Exclusion criteria:

Hypertension Decompensated or acute congestive heart failure Estimated glomerular filtration rate (egfr) less than 60 ml/min/1.73 m² Left ventricular ejection fraction (levf) less than 40% Liver impairment Terminal illness, or cancer Unwilling to give consent or participate

Age

From **45 years** old to **55 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **200**

Actual sample size reached: **190**

Randomization (investigator's opinion)

Randomized

Randomization description

All the subjects were randomly divided into two groups, i.e., 1 and 2. Simple randomization through generation of random numbers was performed on excel sheet after generation of a series of numbers for the total sample size, which were then shuffled and randomized into a sequence using excel, the randomized number list (sequence) was used to allocate subjects in either group (intervention group 1 & 2) sequentially, No allocation concealment was used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty Review Committee - Bahria University Medical & Dental College

Street address

BUMDC, sailor's street, Adjacent PNS-Shifa, DHA

City

Karachi

Postal code

75500

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

FRC-BUMDC-13/2019/Phar-008

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes Mellitus

ICD-10 code

E11.9

ICD-10 code description

Type 2 Diabetes

Primary outcomes

1

Description

Hemoglobin A1c (HbA1c) - Glycated hemoglobin

Timepoint

before intervention and 6, 12 weeks during intervention.

Method of measurement

Levels were measured through blood samples using analyser in laboratory.

2

Description

Fasting Plasma Glucose (FPG)

Timepoint

before intervention and 6, 12 weeks during intervention.

Method of measurement

Levels were measured through blood samples using device for plasma blood glucose.

Secondary outcomes

1

Description

Liver Function Test

Timepoint

before intervention and 6, 12 weeks during intervention.

Method of measurement

Measured by taking samples from the patient.

2

Description

Renal Function Test (RFT)

Timepoint

before intervention and 6, 12 weeks during intervention.

Method of measurement

Measured by taking samples from the patient.

3

Description

Lipid Profile

Timepoint

before intervention and 6, 12 weeks during intervention.

Method of measurement

Measured by taking samples from the patient.

4

Description

Hypoglycemic Events

Timepoint

before intervention and 6, 12 weeks during intervention.

Method of measurement

Through fasting Plasma glucose levels and medical history.

Intervention groups

1

Description

Intervention group 1: Glimepiride (4mg) once daily and Metformin (500mg) three times a day orally for 12 weeks

Category

Treatment - Drugs

2

Description

Intervention group 2: Dapagliflozin (10mg) once daily and Metformin (500mg) three times a day orally for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

National Medical Centre

Full name of responsible person

Muhammad Kamran Yousuf

Street address

National Medical Centre, Phase 1 Defence Housing Authority.

City

Karachi

Postal code

74400

Phone

+92 21 111 222 662

Email

info@nmc.net.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bahria University Medical & Dental College

Full name of responsible person

Muhammad Kamran Yousuf

Street address

Bahria University Medical & Dental College, Sailor Street, DHA, Karachi,

City

Karachi

Postal code

75500

Phone

+92 333 9800961

Email

kmran2010@gmail.com

Web page address

<https://bahria.edu.pk/bumdc/>

Grant name

Self

Grant code / Reference number

Self

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

Yes

Title of funding source

Bahria University Medical & Dental College

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Bahria University Medical & Dental College, Karachi

Full name of responsible person

Muhammad Kamran Yousuf

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Public Health/Community Medicine

Street address

Bahria Medical University Campus, Sailor St, Karachi
Cantonment, Karachi, Karachi City, Sindh

City

Karachi

Province

Sindh

Postal code

75500

Phone

+92 333 9800961

Email

kmran2010@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bahria University Medical & Dental College, Karachi

Full name of responsible person

Muhammad Kamran Yousuf

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Public Health/Community Medicine

Street address

Bahria University Medical & Dental College, Sailor St,
Karachi Cantonment, Karachi, Karachi City, Sindh

City

Karachi

Province

Sindh

Postal code

75500

Phone

+92 333 9800961

Email

kmran2010@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Bahria University Medical & Dental College, Karachi

Full name of responsible person

Muhammad Kamran Yousuf

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Public Health/Community Medicine

Street address

Bahria University Medical & Dental College, Sailor St,
Karachi Cantonment, Karachi, Karachi City, Sindh

City

Karachi

Province

Sindh

Postal code

75500

Phone

+92 333 9800961

Email

kmran2010@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All collected deidentified patient data can be made available, IPD collected for all outcome measures.

When the data will become available and for how long

When the publication is accepted by the journal.

To whom data/document is available

to the publishing journal.

Under which criteria data/document could be used

For analysis purposes with due credit and acknowledgement to the author of this original research. data set can be requested via email once the article is published.

From where data/document is obtainable

By email request from the contact person: Dr. Kamran Yousuf (kmran2010@gmail.com)

What processes are involved for a request to access data/document

Email request

Comments