Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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) - Glycelated 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.
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Karachi
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74400
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+92 21 111 222 662
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bahria University Medical & Dental College
Full name of responsible person
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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
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Person responsible for updating data

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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