Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Prospective Efficacy & Safety study of Monotherapy or Combination therapy with Dapagliflozin in reduction of HbA1C and Body Weight in newly diagnosed or treatment experienced Type II Diabetes Mellitus Patients.

Protocol summary

Study aim

The aim of this prospective observational study is to evaluate the effect of Dapagliflozin oral tablets in reduction HbA1C and body weight after 6 months in Type II Diabetes Mellitus Patients.

Design

Single arm, Open Label, Post Marketing Interventional Trial

Settings and conduct

Medicine Department of Bahawal Victoria Hospital, Bahawalpur. and Diabetes department of Laiq Rafique Foundation, Multan. Patients meeting the eligibility criteria will be included after written informed consent. The decision to start treatment will be made by the Investigators as per clinical practice. Planned no. of patients for this specific study is n=400. Patients will be prescribed Dapagliflozin as per physician discretion. Planned study duration is 24 weeks for a single patient. Through HbA1C, body weight determination patients' response to therapy would be gauged. Patients' follow-up visits would be at Week 02, 04, 12 & 24.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Male & Female (Non-pregnant) Patients ≥ 18 years of age with type II Diabetes Mellitus. • Type II diabetes mellitus patients having controlled diabetes HbA1C 7-10 % or uncontrolled diabetes (HbA1C 10-12%). • Patients having BMI of > 25 kg/m2. • Not Hypersensitive to Dapagliflozin or any of ingredients. Exclusion criteria: • Male & Female Type I Diabetes patients. • Patients having complaints of urinary tract infections, genital infections • Patients with e GFR < 60 mL/min/1.73 m². • Pregnant Females. • Patients with end stage renal disease, or going through dialysis. • Suspected Ketoacidosis patients.

Intervention groups

Intervention group: Dapagliflozin 5 or 10 mg as Per Investigator Discretion

Main outcome variables

1. Reduction in HbA1c from baseline observed at week 12 and 24 after initiation of therapy. 2. Reduction in Body weight from baseline observed at week 2, 4, 12 & 24 after initiation of therapy.

General information

Reason for update

Acronym

DEFINED

IRCT registration information

IRCT registration number: **IRCT20170614034526N5**
Registration date: **2019-10-09, 1398/07/17**
Registration timing: **retrospective**

Last update: **2019-10-09, 1398/07/17**
Update count: **0**

Registration date

2019-10-09, 1398/07/17

Registrant information

Name

Dr. Sharib Syed Muhammad

Name of organization / entity

Hilton Pharma Pvt Ltd

Country

Pakistan

Phone

(021) 111-123-000 Ext:428

Email address

sharibsyed@hiltonpharma.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-12-03, 1397/09/12
Expected recruitment end date
2019-03-31, 1398/01/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Prospective Efficacy & Safety study of Monotherapy or Combination therapy with Dapagliflozin in reduction of HbA1C and Body Weight in newly diagnosed or treatment experienced Type II Diabetes Mellitus Patients.

Public title
Dapagliflozin Efficacy & Safety as Mono or Combination therapy in reduction of HbA1C and Body Weight in Type II Diabetes Mellitus Patients.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male & Female (Non-pregnant) Patients ≥ 18 years of age with type II Diabetes Mellitus. Type II diabetes mellitus patients having controlled diabetes HbA1C 7-10 % or uncontrolled diabetes (HbA1C 10-12%). Patients having BMI of > 25 kg/m2. Not Hypersensitive to Dapagliflozin or any of ingredients.
Exclusion criteria:
Male & Female Type I Diabetes patients. Patients having complaints of urinary tract infections, genital infections Patients with e GFR < 60 mL/min/1.73 m². Pregnant Females. Patients with end stage renal disease, or going through dialysis. Suspected Ketoacidosis patients.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **400**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional Ethical Review Board, Quaid e Azam Medical College Bahawalpur
Street address
Bahawalpur Cantt, Bahawalpur,
City
Bahawalpur
Postal code
63100
Approval date
2018-10-10, 1397/07/18
Ethics committee reference number
470/DME/QAMC

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes Mellitus
ICD-10 code
E08
ICD-10 code description
Type 2 Diabetes mellitus

Primary outcomes

1

Description
Reduction in HbA1c
Timepoint
measured at week 12 & week 24.
Method of measurement
Hba1C test.

2

Description
Body Weight Reduction
Timepoint
week 02, 04, 12 & week 24
Method of measurement
Physical Measurement

Secondary outcomes

1

Description
Serious adverse events (SAE) and non-serious adverse events will be observed. An adverse event (AE) is the appearance or worsening of any undesirable sign, symptom, or medical condition occurring after starting the procedure.
Timepoint

At Week 04, 12 & 24

Method of measurement

Clinical Examination

Intervention groups

1

Description

Intervention group: Dapagliflozin 5 or 10 mg as Per Investigator Discretion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Medicine Department, Quaid-e-Azam Medical College,

Full name of responsible person

Prof. Dr. Qazi Masroor

Street address

Bahawalpur Cantt, Bahawalpur,

City

Bahawalpur

Postal code

63100

Phone

+92 62 2731042

Email

masroorqazi@outlook.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hilton Pharma Pvt Ltd

Full name of responsible person

Dr. Syed Muhammad Sharib

Street address

8th Floor, Progressive Plaza, Beaumont Road, Karachi

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75580

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+92 21 35072224

Email

sharibsyed@hiltonpharma.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hilton Pharma Pvt Ltd

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Medicine Department, Quaid-e-Azam Medical College,

Full name of responsible person

Prof. Dr. Qazi Masroor

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medicine

Street address

Bahawalpur Cantt, Bahawalpur,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Medicine Department, Quaid-e-Azam Medical College,

Full name of responsible person

Prof. Dr. Qazi Masroor

Position

Professor

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Person responsible for updating data

Contact

Name of organization / entity
Hilton Pharma Pvt Ltd

Full name of responsible person
Dr. Syed Muhammad Sharib

Position
Sr. Executive Clinical Research

Latest degree
Bachelor

Other areas of specialty/work
Clinical Research & Medical Affairs

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
To maintain the participants' confidentiality, however data would be made available if Ethics committee and local regulatory bodies demands.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available