

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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.

AgeFrom **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
City
Karachi
Postal code
75580
Phone
+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

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Full name of responsible person
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Position
Professor
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Other areas of specialty/work
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+92 62 2731042
Email

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

Street address

8th Floor, Progressive Plaza, Beaumont Road, Karachi

City

Karachi

Province

Sindh

Postal code

75580

Phone

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