

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\geq$  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/m<sup>2</sup>. • 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 m<sup>2</sup>. • 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  $\geq 18$  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/m<sup>2</sup>. 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 m<sup>2</sup>. 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 &amp; week 24.

**Method of measurement**

Hba1C test.

**2****Description**

Body Weight Reduction

**Timepoint**

week 02, 04, 12 &amp; 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

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Bahawalpur Cantt, Bahawalpur,

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**Person responsible for scientific inquiries**

**Contact**

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Medicine Department, Quaid-e-Azam Medical College,

**Full name of responsible person**

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sharibsyed@hiltonpharma.com

## 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