

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of Dapagliflozin in diabetic and nondiabetic patients with Acute heart failure

#### Protocol summary

##### Study aim

To evaluate the efficacy of dapagliflozin in diabetic and non diabetic patients with acute heart failure

##### Design

Prospective randomized control study

##### Settings and conduct

Pharmacology department of public sector hospital, National University of medical sciences in collaboration with cardiology department of a public sector hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Male/Female patients 18 years and above 2. Diagnosis of acute decompensated heart failure made on admission 3. Left ventricular Ejection fraction  $\leq$  40% Any two of the following signs and symptoms a) Dyspnea at rest or minimal exertion b) Peripheral edema c) Ascites d) 5-pound weight gain (rapid) e) Signs of congestion on X-ray 4. eGFR  $\geq$  30ml/min Exclusion Criteria: 1. Cardiogenic shock 2. urgent hospitalization for acute heart failure primarily triggered by pulmonary embolism, cerebrovascular accident, or acute myocardial infarction (AMI) 3. Current hospitalization for acute heart failure not caused primarily by intravascular volume overload; Type 1 Diabetes mellitus 4. History of Diabetic ketoacidosis 5. History of hepatic impairment 6. Known allergy to SGLT 2 inhibitors 7. women pregnant or breast feeding

##### Intervention groups

Control and study Groups The control group will be prescribed with conventional treatment for acute heart failure the study group will be prescribed with Dapagliflozin as add on therapy to the conventional treatment for Acute heart failure

##### Main outcome variables

1. Effect of dapagliflozin in causing pulmonary decongestion. 2. Effect of dapagliflozin in improving quality of life assessed by KCCQ 3. Effect of dapagliflozin on eGFR

#### General information

##### Reason for update

##### Acronym

AHF( Acute Heart Failure)

##### IRCT registration information

IRCT registration number: **IRCT20220529055013N1**

Registration date: **2022-06-23, 1401/04/02**

Registration timing: **prospective**

Last update: **2022-06-23, 1401/04/02**

Update count: **0**

##### Registration date

2022-06-23, 1401/04/02

##### Registrant information

##### Name

Fauzia Gilani

##### Name of organization / entity

National University of Science & Technology

##### Country

Pakistan

##### Phone

+92 51 2300714

##### Email address

fauziagilani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-01, 1401/04/10

##### Expected recruitment end date

2022-12-31, 1401/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Efficacy of Dapagliflozin in diabetic and nondiabetic patients with Acute heart failure

## Public title

Dapagliflozin in Acute Heart failure

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

1. Male/Female patients 30 years and above  
2. Diagnosis of acute decompensated heart failure made on admission based on any two of the following signs and symptoms  
a) Dyspnea at rest or minimal exertion  
b) Peripheral edema  
c) Ascites  
d) 5-pound weight gain (rapid)  
e) Signs of congestion on X-ray  
3. Left ventricular Ejection fraction  $\leq$  40%  
4. eGFR  $\geq$  30ml/min

### Exclusion criteria:

Cardiogenic shock; urgent hospitalization for acute heart failure primarily triggered by pulmonary embolism, cerebrovascular accident, or acute myocardial infarction  
Current hospitalization for acute heart failure not caused primarily by intravascular volume overload  
Type 1 Diabetes mellitus  
History of Diabetic ketoacidosis  
History of hepatic impairment  
Known allergy to SGLT 2 inhibitors  
Women pregnant or breast feeding

## Age

From 30 years old

## Gender

Both

## Phase

4

## Groups that have been masked

- Participant

## Sample size

Target sample size: 160

## Randomization (investigator's opinion)

Randomized

## Randomization description

The participants will be divided into groups as control and study groups. The study drug (dapagliflozin) will be prescribed as add-on therapy to the conventional treatment of acute heart failure in a 1:1 simple randomization among the individuals taking participation in the study.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The study participants will be blinded.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary IDs

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics review committee of public sector hospital

##### Street address

the mall, abid majeed road

##### City

Rawalpindi

##### Postal code

46000

#### Approval date

2022-03-31, 1401/01/11

#### Ethics committee reference number

S/017/2022

## Health conditions studied

### 1

#### Description of health condition studied

Heart failure with reduced ejection fraction

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Improvement in symptoms and quality of life of heart failure patients admitted with acute decompensation

#### Timepoint

At admission (baseline), followed at Day 1, day 7 and day 30

#### Method of measurement

Kansas city cardiomyopathy questionnaire (KCCQ)

### 2

#### Description

Effect of drug on kidney function

#### Timepoint

At day 0, 1, 7 and 30

#### Method of measurement

estimated glomerular filtration rate (eGFR)

## Secondary outcomes

### 1

#### Description

Improvement in Hemoglobin levels

#### Timepoint

Day 0, 1, 7 and day 30

#### Method of measurement

complete blood count

2

**Description**

Blood pressure

**Timepoint**

Day 0,1 7 and 30

**Method of measurement**

Sphygmamometer

**Intervention groups**

1

**Description**

Intervention group: Tab Dapagliflozin 10 mg orally as add on therapy to the conventional treatment will be prescribed to the study participants

**Category**

Treatment - Drugs

2

**Description**

Control group: The participants in this group will be prescribed with the conventional treatment for heart failure

**Category**

N/A

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Public Sector hospital in Rawalpindi ( cardiology department)

**Full name of responsible person**

Syedah Fauzia Fatima Gilani

**Street address**

the mall, abid majeed road

**City**

Rawalpindi

**Postal code**

46000

**Phone**

+92 335 5858327

**Email**

fauziagilani@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Public Sector medical University

**Full name of responsible person**

Mudassar Noor

**Street address**

The mall, Abid Majeed Road

**City**

Rawalpindi

**Postal code**

46000

**Phone**

+92 51 9270677

**Email**

smilingdr@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Public Sector medical University

**Proportion provided by this source**

50

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

National University of medical Sciences

**Full name of responsible person**

Syedahh Fauzia Fatima Gilani

**Position**

Mphil Trainee

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

The mall, Abid Majeed road

**City**

Rawalpindi

**Province**

punjab

**Postal code**

46000

**Phone**

+92 51 2300714

**Email**

fauziagilani@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Public Sector Medical College

**Full name of responsible person**

Syedah Fauzia Fatima Gilani

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

Yes - There is a plan to make this available

**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**

Yes - There is 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**

Not applicable

**Title and more details about the data/document**

title: Results. Tables and graphs of primary outcome and secondary outcome will be shared.

**When the data will become available and for how long**

it will be given in the duration of 10 months to 36 months after publishing. It will be available lifelong

**To whom data/document is available**

everyone

**Under which criteria data/document could be used**

everyone who want to take advantage of this trial results will be allowed for the service of humanity.

**From where data/document is obtainable**

They can talk to principal investigator of this trial Syedah Fauzia Fatima Gilani. E-mail: fauziagilani@gmail.com

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

Email

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

Public Sector medical College

**Full name of responsible person**

Syedah Fauzia Fatima Gilani

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**Other areas of specialty/work**

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