

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 deptment 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 ≥ 30 ml/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

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Rawalpindi

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Public Sector Medical College

Full name of responsible person

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Position

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Person responsible for updating data

Contact
Name of organization / entity
Public Sector medical College
Full name of responsible person
Syedah Fauzia Fatima Gilani
Position
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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