Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 deprtment 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 ≤ 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 ≥ 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 ≤ 40% 4. eGFR ≥ 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 in 1:1 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,day7 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
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
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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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Person responsible for updating data

Contact
Name of organization / entity
Public Sector medical College
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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