Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Empagliflozin on the severity of heart failure symptoms and Ecocardiography parameters in patients with congenital heart diseases with left-to-right shunt: a triple-blind, randomized, placebo-controlled trial

Protocol summary

Study aim
Improving the severity of heart failure symptoms and echocardiographic parameters in CHD patients with left-to-right shunt by administering empagliflozin

Design
A triple blind, randomised, placebo-controlled clinical trial, prospective study, superiority, parallel, phase 3, performed on 44 patients, for randomisation permuted block randomisation technique with blocks of size 6 and 2 is done using the website https://www.sealedenvelope.com.

Settings and conduct
44 patients with heart failure caused by congenital defects of the heart septum who are admitted to the paediatric cardiology department of Imam Reza Hospital are included in the study. Patients are randomly assigned to 2 groups intervention and control, in triple-blind manner, by assigning codes A and B to the drug and placebo groups, which only the nurse knows about the type of codes. During hospitalisation primary and secondary outcomes are evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: CHD patients with left-to-right shunt and heart failure aged one month to 18 years Exclusion criteria: patients with various types of cardiomyopathy myocarditi, pericarditis and cardiac tamponade thiamine deficiency severe anemia thyrotoxicosis ,pulmonary infection CKD (GFR < 20 ml/min/m2) dialysis

Intervention groups
The intervention group includes patients who receive empagliflozin tablets during hospitalization along with a standard drug regimen that includes ACEI/ARB, digoxin, and diuretics. The control group includes patients who receive placebo during hospitalization along with a standard drug regimen that includes ACEI/ARB, digoxin, and diuretics. Finally, the severity of heart failure symptoms and echocardiography parameters in two groups are compared.

Main outcome variables
Echocardiography parameters: TRPG (tricuspid regurgitation peak gradient) Left to Right shunt gradient Left ventricular Ejection fraction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120520009801N11**
Registration date: **2024-02-04, 1402/11/15**
Registration timing: **prospective**

Last update: **2024-02-04, 1402/11/15**
Update count: **0**

Registration date
2024-02-04, 1402/11/15

Registrant information

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Amir Hooshang Mohammadpour

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-11, 1402/12/21
Expected recruitment end date
2025-06-25, 1404/04/04
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Empagliflozin on the severity of heart failure symptoms and Ecocardiography parameters in patients with congenital heart diseases with left-to-right shunt: a triple-blind, randomized, placebo-controlled trial

Public title
Evaluation of the effect of Empagliflozin on the severity of heart failure symptoms and echocardiography parameters in patients with congenital heart diseases with left-to-right shunt
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with congenital heart diseases with left-to-right shunt Heart failure One month to 18 years
Exclusion criteria:
Patients with various types of cardiomyopathy Patients with myocarditis Patients with pericarditis and cardiac tamponade Patients with thiamine deficiency (beriberi) based on clinical symptoms Patients with severe anemia Patients with thyrotoxicosis Presence of pulmonary infection Chronic kidney disease in GFR < 20 ml/min/173 m2 Patients on dialysis
Age
From **1 month** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomly assign people to the study groups while guaranteeing the equality of the sample size of the groups, permuted block randomisation technique with blocks of size 6 and 2 is done using the website https://www.sealedenvelope.com. For example, the allocation result could be 11 blocks of 2 with different permutations. Type of randomization: Block Allocation Concealment: Using non-transparent sealed envelopes with a random sequence obtained from the random allocation step. Since our data will be completed over time and patients will gradually enter the study, patients are allocated to one of the control or intervention groups based on the time of entry into the study and also the sequence obtained in the randomisation stage. These codes are available to the researcher present at the hospital. It should be mentioned that this researcher is fully aware of the codes. Also, the drug or placebo is available to the researcher based on the code (A or B) and he is fully aware of which one is empagliflozin or placebo. The phone number of the researcher is also available to the patients who can call him whenever any problem arises. (This researcher is not involved in the prescription, nor in the treatment evaluation or data analysis, and is solely responsible for maintaining the codes and providing the medicine to the patients based on the random code determined by the doctor). The code assigned by him is recorded in the CRF form.
Blinding (investigator's opinion)
Triple blinded
Blinding description
After the codes were prepared and given to the researcher, if the criteria for entering the study are completed and based on the codes, the patient is randomly assigned to one of the groups. The relevant code is recorded in the CRF form and the researcher considers the medicine or placebo for the patient based on the assigned code. The patient is introduced to a nurse and the prescription of drugs is done by the nurse (therapist), meanwhile, after the patient takes the drug or placebo during the hospitalization period, the evaluator (doctor) who is different from the therapist (nurse) and does not know which medicine the patient has received and only knows the assigned code, performs the relevant evaluations. After recording, the results are given in the form of codes to the person to analyse the data and hence the data is also processed without the analyst knowing which medication is being prescribed to the patient and all information is recorded and stored confidentially without mentioning the name of the patient.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Third floor of Ghoreshi building, Next to Hoveyzeh Cinema, Daneshgah Street, Mashhad
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Razavi Khorasan
Postal code
9138813944
Approval date
2023-10-21, 1402/07/29
Ethics committee reference number
IR.MUMS.REC.1402.229

Health conditions studied

1

Description of health condition studied
Congenital heart disease with left to right shunt causing heart failure symptoms
ICD-10 code
Q21
ICD-10 code description
Congenital malformations of cardiac septa

Primary outcomes

1

Description
TRPG (tricuspid regurgitation peak gradient)
Timepoint
At the beginning and at the end of hospitalization
Method of measurement
Echocardiography

2

Description
Left to Right shunt gradient
Timepoint
At the beginning and at the end of hospitalization
Method of measurement
Echocardiography

3

Description
Left ventricular Ejection fraction
Timepoint
At the beginning and at the end of hospitalization
Method of measurement
Echocardiography

Secondary outcomes

1

Description
Heart failure symptoms
Timepoint
Daily
Method of measurement
Age-based Ross classification for heart failure in children

2

Description
Vital signs
Timepoint
Daily
Method of measurement
Sphygmomanometer, Thermometer, Vital sign monitoring device , Nurse

3

Description
Oxygen saturation (Spo2)
Timepoint
Daily
Method of measurement
Pulse oximeter

4

Description
Weight
Timepoint
Daily
Method of measurement
Scale

5

Description
Inflammatory markers:CRP and ESR
Timepoint
At the beginning and at the end of hospitalisation
Method of measurement
laboratory tests

Intervention groups

1

Description
Intervention group: patients who receive empagliflozin tablets during hospitalization along with a standard drug regimen that includes ACEI/ARB, digoxin, and diuretics
Category
Treatment - Drugs

2

Description
Control group: patients who receive placebo during hospitalization along with a standard drug regimen that includes ACEI/ARB, digoxin, and diuretics.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Paediatric cardiology department of Imam Raza hospital

Full name of responsible person
Amirhooshang Mohamadpoor

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Sponsors / Funding sources

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https://v-research.mums.ac.ir/moavenat/2021-04-06-05-57-55

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

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
Mashhad University of Medical Sciences

Full name of responsible person
Amir Hooshang Mohammadpour

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentifiable individuals
When the data will become available and for how long
Six months after the results are published
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
Use in clinic to improve disease severity, In the condition that safety and efficacy are confirmed in the study
From where data/document is obtainable
Dr amirhoushang mohamadpour Email: Mohamadpoorah@mums.ac.ir
What processes are involved for a request to access data/document
Reply to email within a maximum of one week
Comments