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Does dapagliflozin change heart function as detected by ultrasound in patients with heart failure?

Submission date
09/05/2022

Recruitment status
No longer recruiting

Registration date
06/07/2022

Overall study status
Completed

Last Edited
09/05/2023

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Heart failure with reduced ejection fraction (HFrEF) happens when the heart muscle cannot pump forcefully enough to move the blood around the body. The effects on the heart muscle of the sodium-glucose co-transporter-2 inhibitor dapagliflozin, which is used to treat type 2 diabetes and heart failure, are not clear. Therefore, the aim of this study is to determine the effect of the addition of dapagliflozin to conventional treatment in patients with HFrEF.

Who can participate?
Patients aged 18 or over with mild to severe HFrEF.

What does the study involve?
Non-invasive imaging was used to compare the function of the heart muscle in patients with HFrEF given dapagliflozin in addition to their conventional treatment for HF for 6 months with a control group of patients with HFrEF receiving only their conventional HF treatment for the same time period.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
Omar Yacef Hospital (Algeria)

When is the study starting and how long is it expected to run for?
August 2021 to March 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Professor Nassime Zaoui, nassime.zaoui@outlook.com

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Impact of dapagliflozin on echocardiographic parameters in patients with heart failure and reduced ejection fraction

Study objectives
Dapagliflozin has proven its effectiveness in reducing morbi-mortality in patients with heart failure. However, its effects on systolic and diastolic echocardiographic function are less known. The objective of this study is to describe the impact of the addition of dapagliflozin to conventional treatment on echocardiographic parameters in patients with HFrEF <40% compared to a control group of patients after 6 months of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This is an observational, case-control study, which does not require ethics approval under Algerian law because the treatment is already approved in this pathology and ultrasound remains a non-invasive and mandatory examination in the usual follow-up of these patients.

Primary study design
Observational

Study design
Observational single-center non-randomized longitudinal case-control study

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Heart failure and reduced ejection fraction

Interventions
A group of patients with HFrEF<40% in stage II to IV of NYHA receiving classic HF treatment with dapagliflozin 10 mg/day were compared with a group of patients with the same profile receiving classic HF treatment only for 6 months using echocardiography at a follow-up of 7 months for ejection fraction (EF), left ventricular dysfunction (LVd), systolic pulmonary pressure (sPAP) and longitudinal strain

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dapagliflozin

Primary outcome(s)
1. Heart failure functional classification assessed using NYHA stage at the first visit
2. Hospitalization rate recorded in our HF hospital registry at the end of the study
3. Ejection fraction (EF) measured by an echocardiogram (ECG) at the first visit, 3 months, and at 7 months (5-8 months) follow-up

Key secondary outcome(s)
1. Mean left ventricular dysfunction (LVd) measured by an echocardiogram (ECG) at the first visit, 3 months, and at 7 months (5-8 months) follow-up
2. Systolic pulmonary pressure (sPAP) measured by an ECG at the first visit, 3 months, and at 7 months (5-8 months) follow-up
3. Mean longitudinal Strain measured by ECG at the first visit, 3 months, and at 7 months (5-8 months) follow-up
4. Urinary tract infection assessed by interrogation (presence of burning urination) and urine strip (Labstix) at each consultation (at the first visit, 3 months, and at 7 months (5-8 months) follow-up) and if necessary cytobacteriological urine examination (in the case of burning urination)

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Patients with HFrEF<40% in NYHA stage II to IV, who presented to our department during the recruitment period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
43

Key exclusion criteria
Type 1 diabetes

Date of first enrolment
15/08/2021

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
Algeria

Study participating centre
Omar Yacef Hospital
Draa Ben Khedda
Tizi Ouzou
Algeria
1510

Sponsor information

Organisation
Mouloud Mammeri University of Tizi-Ouzou

ROR
https://ror.org/050ktqq97

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2022	09/05/2023	Yes	No