

Coenzyme Q10 supplementation in heart failure with preserved ejection fraction patients

Submission date 21/02/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 02/03/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 22/02/2018	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Heart failure occurs when the heart is not able to pump enough blood that the body needs. Heart failure with preserved ejection fraction (HFpEF) (a type of heart failure where the left ventricle pumps with each an amount of blood greater than 50%) is a leading cause of morbidity and mortality without an established best course treatment. Diastolic dysfunction (the decline of the performance of one of the ventricles) is a hallmark of HFpEF. This is associated with altered myocardial bioenergetics and oxidative stress. No previous study has examined the effects of coenzyme Q10, a bioenergizer and antioxidant, on left ventricle (LV) diastolic function of HFpEF patients. The aim of this study is to investigate the effects of coenzyme Q10 on LV diastolic function in HFpEF patients.

Who can participate?

Adults aged 45 and older who have heart failure.

What does the study involve?

Participants are allocated to one of two groups. Those in the first group receive a capsule of coenzyme Q10 (100 mg) three times a day for 30 days. Those in the second group continue with their usual care. Participants are assessed for their heart function after 30 days using an ECG and a blood test.

What are the possible benefits and risks of participating?

CoQ10 is available over the counter as a dietary supplement elsewhere. Potential benefits of CoQ10 supplementation have been recognized with particular reference to energy supplement and cardiovascular and neurodegenerative diseases. CoQ10 has an excellent safety record. The safety of high doses of orally-ingested CoQ10 over long periods is well documented in human subjects. The side effects reported in human studies are generally limited to mild gastrointestinal symptoms such as nausea and stomach upset seen in a small number of subjects. No adverse effects were observed with daily doses ranging from 600 to 1200 mg in two trials on Huntington's and Parkinson's diseases. In cardiovascular disease patients CoQ10 dosages generally range from 100 to 300 mg a day. Caution should be given to the patients who are taking Coumadin given the similarities of CoQ10 with vitamin K.

Where is the study run from?
dr. Kariadi Hospital (Indonesia)

When is the study starting and how long is it expected to run for?
April 2017 to September 2018

Who is funding the study?
Ministry of Research, Technology and Higher Education Indonesia

Who is the main contact?
1. Dr Mochamad Ali Sobirin (Scientific)
2. Dr Sodiqur Rifqi (Scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
486/EC/FK-RSDK/VII/2017

Study information

Scientific Title

Effect of short term coenzyme Q10 supplementation on diastolic function in heart failure with preserved ejection fraction patients

Study objectives

Coenzyme Q10 supplementation can improve left ventricular diastolic function in patients with heart failure with preserved ejection fraction.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Head of Ethical Clearance in Faculty of Medicine, Diponegoro University, 01/08/2017: ref: 486/EC /FK-RSDK/VII/2017

Primary study design

Interventional

Study design

Interventional single-centre randomised parallel unblinded study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Heart failure

Interventions

Eligible participants are randomly allocated to one of two groups. Those in the first group receive coenzyme Q10 100 mg three times a day in a capsule for 30 days. Those in the second group receive treatment as usual.

The randomization ratio was 1:1 for coenzyme Q10 or without coenzyme Q10 using permuted block. Standard therapies for risk factor and symptom control were at the discretion of treating physicians and required to be unchanged within the 4 weeks prior to randomization.

Follow up will be in every week and after 1 month by phone call or during hospital visit. Participants are also followed up with blood tests and ECGs.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Coenzyme Q10 (Qten 100 mg, by Novell pharmaceutical laboratories)

Primary outcome(s)

Diastolic function is measured using the two dimensional and doppler echocardiography at baseline and 1 month after intervention.

Key secondary outcome(s)

1. Plasma malondialdehyde level is measured using HPLC procedure at baseline and 1 month after intervention
2. Quality of life is measured using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) at baseline and 1 month after intervention

Completion date

01/09/2018

Eligibility**Key inclusion criteria**

1. Men or women and age > 45 years old
2. Typical signs and symptoms of chronic heart failure (CHF) (New York Association Class 2-3)
3. Normal ejection fraction on echocardiography (EF ≥50%)
4. Evidence of diastolic dysfunction on non-invasive imaging (at least diastolic dysfunction grade 1 ($E/A \leq 0.8 + E > 50$ cm/s or $E/A > 0.8 - < 2$) with at least 1 criteria below required: (1) septal $e' < 7$ cm/sec or lateral $e' < 10$ cm/sec, (2) average $E/e' > 14$, (3) LA volume index > 34 ml/m², and (4) TR velocity > 2.8 m/sec
5. Stable medical therapy for 4 weeks prior to randomization
6. Informed consent available

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Chronic atrial fibrillation
2. Acute coronary syndrome or coronary revascularization within 60 days
3. Clinically significant valvular disease
4. Significantly low systolic blood pressure (<100) mmHg and high blood pressure
5. Patients with a prior LVEF reading <40%
6. Known infiltrative cardiomyopathy (e.g. amyloidosis), hypertrophic cardiomyopathy or chronic pericardial disease
7. Dyspnea or edema due to non-cardiac cause such as pulmonary disease, anemia (Hb < 8.0 g/dl)
8. Any sign of serious infection during study
9. On treatment of corticosteroid and immunosuppressant drugs
10. Current smoker more than 30 cigarettes/day
11. Inability/refusal to provide informed consent
12. Poor echo window

Date of first enrolment

01/11/2017

Date of final enrolment

01/02/2018

Locations

Countries of recruitment

Indonesia

Study participating centre

dr. Kariadi Hospital

dr. Sutomo Road No.16

Semarang

Indonesia

50244

Sponsor information

Organisation

Diponegoro University

ROR

<https://ror.org/056bjta22>

Funder(s)

Funder type

Government

Funder Name

Ministry of Research, Technology and Higher Education Indonesia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mochamad Ali Sobirin, MD, PhD (email: dr_alibirin@yahoo.com)

IPD sharing plan summary

Available on request