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Coenzyme Q10 supplementation in heart failure with preserved ejection fraction patients

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Interventional single-centre randomised parallel unblinded study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, pelase use contact details to request a participant information sheet

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

Secondary outcome measures
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 at baseline and 1 month after intervention

Overall study start date
01/04/2017

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 ≤ 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

Age group
Adult

Sex
Both

Target number of participants
50

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 immunosupresant 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
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Sponsor information

Organisation
Diponegoro University

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Sponsor type
University/education

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ROR
https://ror.org/056bjta22

Funder(s)

Funder type
Government

Funder Name
Ministry of Research, Technology and Higher Education Indonesia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Additional documentation is available in PDF format.

Intention to publish date
01/06/2018

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