ISRCTN94506234 https://doi.org/10.1186/ISRCTN94506234

Coenzyme Q10 as adjunctive treatment of chronic heart failure: a randomised, double-blind, multicentre trial with focus on SYMptoms, BIOmarker status (Brain-Natriuretic Peptide [BNP]), and long-term outcome (hospitalisations/mortality)

Submission date
23/03/2007

Recruitment status
No longer recruiting

Registration date
23/04/2007

Overall study status
Completed

Last Edited
06/10/2014

Condition category
Circulatory System

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P-6708

Study information

Scientific Title

Acronym
Q-SYMBIO

Study objectives
Adjuvant treatment of heart failure patients with coenzyme Q10 versus placebo will improve the patients symptoms and functional status and affect positively morbidity (unplanned cardiovascular hospitalisations) and mortality as a composite endpoint.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Scientific Committees for Copenhagen and Frederiksberg Municipality, 27/06/2003, ref: (KF) 02-023/03

The trial will respect the Helsinki (II) declaration, and have been evaluated and accepted by the relevant ethics committee(s). Written consent is obtained from each patient and the anonymity of each patient will be respected and ensured.

Study design
Randomised placebo-controlled parallel multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Established chronic heart failure due to predominantly ishaemic heart disease or cardiomyopathy.

Interventions
Capsules containing 300 mg of CoQ10 daily or similar placebo capsules containing soy oil.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Coenzyme Q10

Primary outcome measure
1. Major Adverse Cardiovascular Events (MACE) defined as:
a. unplanned hospitalisations due to worsening heart failure
b. cardiovascular death
c. urgent cardiac transplantation, or
d. mechanical support
Using a time to first event analysis (composite endpoint)
2. Physicians assessment:
a. New York Heart Association (NYHA) classification
b. Six Minutes hall Walk distance (6MW)

Secondary outcome measures
1. NYHA symptom class, serum pro-BNP, echocardiography
2. Patients assessment:
a. dyspnea and fatigue (Visual Analogue Scale [VAS])
b. evaluation of change in symptoms (VAS)

Overall study start date
01/04/2003

Completion date
01/10/2008

Eligibility

Key inclusion criteria
1. Patients above the age of 18 years with chronic heart failure
2. New York Heart Association (NYHA) class III or IV with ability to participate in a six-minutes walk test
3. Stable on maximum current heart failure therapy
4. Informed consent obtained

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
550

Key exclusion criteria
1. Myocardial infarction, unstable angina, percutaneous coronary intervention or cardiac surgery within the past six weeks
2. Heart failure due to congenital heart disease
3. Uncorrected valvular heart disease, planned valve surgery
4. Urgent waiting-list for heart transplantation (status-one patients)
5. Restrictive (including amyloid) cardiomyopathy
6. Alcoholic heart disease
7. Acute myocarditis
8. Patients on continuous intravenous (i.v.) therapy for heart failure
9. Patients with mechanical assist device
10. Stroke within the past six weeks
11. Women of childbearing potential and lactating females
12. Supplementary CoQ10 intake within the last month before run-in
13. Six-minutes walk distance greater than 450 metres
14. Life expectancy less than one year due to non-cardiac causes
15. Psychosocial instability or anticipated problems with compliance
16. Participation in another controlled trial
17. Lack of informed consent
18. Allergic to the constituents of the test medication (ubidecarenone, soy oil, alpha-tocopherol, gelatine)
19. Other serious disease including tumourous disease
20. Participation in other clinical trials

Date of first enrolment
01/04/2003

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
Australia

Austria

Denmark

Hungary

India

Malaysia

Poland

Slovakia

Sweden

Study participating centre
Pharma Nord ApS
Vejle
Denmark
7100

Sponsor information

Organisation
Pharma Nord ApS (Denmark)

Sponsor details
Sadelmagervej 30-32
Vejle
Denmark
7100

Sponsor type
Industry

Website
http://www.pharmanord.dk/wstore/contentServlet

ROR
https://ror.org/00hz19x62

Funder(s)

Funder type
Industry

Funder Name
Pharma Nord ApS (Denmark)

Funder Name
International Coenzyme Q10 Association (Italy)

Funder Name
Kaneka Corporation of Osaka (Japan)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2014		Yes	No