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Pilot study for the treatment of heart failure with Pycnogenol

Submission date 06/08/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/12/2007	**Overall study status** Completed	
Last Edited 06/12/2007	**Condition category** Circulatory System	

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
HF2007AM

Study information

Scientific Title

Study objectives
Pycnogenol, standardized French maritime pine bark extract, has shown beneficial effects on various cardiovascular health parameters such as blood pressure and cholesterol levels in both preclinical as well as clinical trials. The aim of this study is to investigate the effect of 200 mg daily of Pycnogenol on objective and subjective symptoms in patients with heart failure New York Heart Association (NYHA) status II.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethics Committee at Okuizumo Hospital in Shimane prefecture, Japan, on 24 May 2007

Study design
12 week randomised, double-blind placebo-controlled matched pairs 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
Heart failure

Interventions
200 mg Pycnogenol (standardized extract of French maritime pine bark) or placebo for 12 weeks. Patients receiving diuretics before enrollment should continue usage and not change dose/intake intervals. Drug intake will be controlled and any unwanted effect reported at each visit.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Patients undergo tests for maximal workload and pressure-heart product at 0, 4, 8, and 12 weeks after enrollment.

Maximal workload: As determined by a symptom-limited bicycle exercise test in the seated position.
Pressure-heart rate product: Immediately after 2 min work at 50 W, systolic blood pressure and heart rate are recorded. Pressure-heart rate product is calculated by units of systolic blood pressure (mmHg) x heart rate per minute divided by 100.

Secondary outcome measures
Patients will report scores for dyspnea and fatigue for the foregoing 4 weeks upon enrollment (baseline) and repeat evaluation at 4, 8, and 12 weeks after enrollment. Symptom scores will be evaluated by asking patients about the severity of the following symptoms:
1. Early fatigability
2. Dyspnea
3. General capability
4. Lassitude
5. Feeling depressed
6. Anxiety

Scores range from 0 = not present, 1 = occasionally mild, 2 = frequently mild, 3 = moderate, 4 = severe.
Blood analysis: Routine clinical chemistry in addition to the assays of BNP (NT-proBNP), C-Reactive Protein and troponin T.

Overall study start date
10/08/2007

Completion date
31/07/2008

Eligibility

Key inclusion criteria
Patients over 40 years of age with chronic congestive heart failure (NYHA class II), known for at least 6 months which were previously untreated or treated with a diuretic and/or a low dose of an ACE inhibitor. Patients must have an exercise capacity of at least 75 watts as assessed by seated bicycle ergometry.

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
30

Key exclusion criteria
1. NYHA status I, III or IV
2. Treatment with digitalis within the previous 6 months
3. Exercise capacity of >75 W for 2 min at the test during run-in
4. Unstable angina or myocardial infarction within the last 6 months
5. Atrial fibrillation or ventricular arrhythmia greater than or equal to Lown III
6. Cardiac valvular disease or hypertrophic cardiomyopathy
7. Significant hypertension or hypotension (< 60 mmHg or greater than or equal to 105 mmHg diastolic or < 90 mmgH or > 175 mmHg systolic)
8. Electrolyte disturbances, hyperuricemia, hypovolemia
9. Impaired renal function (creatinine >1.8 mg/dL) or hepatic function
10. Obstructive airways disease
11. Insulin-dependent diabetes
12. Malignant or other serious disease
13. Hypersensitivity to study drug
14. Pregnancy, unreliable contraception, breast-feeding mothers
15. Participation in another clinical trial within the last 6 weeks

Date of first enrolment
10/08/2007

Date of final enrolment
31/07/2008

Locations

Countries of recruitment
Japan

Study participating centre
Kyoto University Graduate School of Medicine
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Sponsor information

Organisation
Kyoto University (Japan)

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Sponsor type
University/education

Website
http://www.kyoto-u.ac.jp/index-e.html

ROR
https://ror.org/02kpeqv85

Funder(s)

Funder type
University/education

Funder Name
Kyoto University, Cardiomyopathy and Myocarditis Research Fund (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