ISRCTN42524037 https://doi.org/10.1186/ISRCTN42524037

Exercise training in Diastolic Heart Failure - Pilot study: a prospective, randomised, controlled study to determine the effects of physical training on exercise capacity and quality of life

Submission date
04/07/2007

Recruitment status
No longer recruiting

Registration date
27/09/2007

Overall study status
Completed

Last Edited
08/01/2024

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

Contact name
Dr Frank Edelmann

Contact details
Robert- Koch- Str. 40
Gottingen
Germany
37073
+49 (0)551 392658
fedelmann@med.uni-goettingen.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Exercise training in Diastolic Heart Failure - Pilot study: a prospective, randomised, controlled study to determine the effects of physical training on exercise capacity and quality of life

Acronym
Ex-DHF-P

Study objectives
Supervised combined endurance and strength exercise training for three months, two to three times/week improves the exercise capacity and quality of life in patients with diastolic heart failure compared to patients in a non-training control group.

Please note that as of 01/11/2007 this trial has now been completed. The previous anticipated end date of this trial was 30/09/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the ethics committees of the Universities of Gottingen, Berlin, Munich (Germany) on the 14th September 2006 (ref: 38/9/06), following by amendment 1 on 22nd January 2007 and amendment 2 on 7th March 2007.

Study design
Multicentre prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Diastolic heart failure

Interventions
Once randomised, patients will either participate in an combined endurance and strength exercise training two to three times/week for three months or perform their usual activities.

After three months and the second visit all patients participate in the training for another three months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Change in peak maximal oxygen uptake (VO2), measured at 3 months.

Secondary outcome measures
1. Change in quality of life
2. Change in early left ventricular filling-to-peak early diastolic myocardial velocity ratio (E/E' ratio)
3. Change in six-minute walking distance
4. Change in N-Terminal pro-B-type Natriuretic Peptide (NT-proBNP) and other parameters of neurohumoral activation
5. Change in Heart Rate Variability (HRV) and Heart Rate Turbulence (HRT)
6. Change in blood levels of parameters of collagen turnover, metabolic syndrome and inflammation
7. Change in parameters of diastolic dysfunction:
7.1. Early-to-Atrial left ventricular filling ratio (E/A ratio)
7.2. Early left ventricular filling Deceleration Time (EDT)
7.3. Isovolumic Relaxation Time (IVRT)
7.4. Systolic-to-Diastolic pulmonary venous flow ratio (S/D ratio)
7.5. Pulmonary Venous peak Atrial contraction Reversed velocity (PVAR)
7.6. Colour M-Mode flow propagation Velocity (Vp)
7.7. Doppler echocardiography-derived index of myocardial performance (TEI-Index)
7.8. Left Ventricular mass (LV-mass)
7.9. Left Ventricular volume (LV-volume)
7.10. Left Atrial volume (LA-volume)
8. Severity of diastolic dysfunction (echocardiography)
9. Change in endothelial function, safety, compliance, cardiovascular morbidity and mortality

Secondary outcomes are measured at 3 and 6 months

Overall study start date
01/10/2006

Completion date
01/11/2007

Eligibility

Key inclusion criteria
1. At least one of the following risk factors for the development of a diastolic dysfunction:
1.1. Diabetes
1.2. Hypertension
1.3. Smoking

1.4. Hyperlipidaemia
1.5. Overweight
2. Aged greater than or equal to 45 years
3. Written informed consent
4. New York Heart Association (NYHA) II or III
5. Diastolic dysfunction greater than or equal to grade one (echocardiographically determined)
6. Left Ventricular Ejection Fraction (LVEF) greater than or equal to 50%

Participant type(s)
Patient

Age group
Adult

Lower age limit
45 Years

Sex
Both

Target number of participants
60 (40 versus 20)

Total final enrolment
64

Key exclusion criteria
1. Diseases limiting the validity of consent (psychiatric diseases, dementia etc.,)
2. Change in medication within the last two weeks
3. Limited exercise capacity due to musculo-skeletal diseases or pulmonary disease
4. Myocardial Infarction (MI) or bypass surgery in the patient's history or clinically significant Coronary Artery Disease (CAD) (angina or known untreated stenosis of more than 50%) or peripheral arterial obstructive disease greater than or equal to IIa
5. Pregnant or nursing women and women before menopause without sufficient contraception
6. Participaton in another study currently or within the last 30 days

Date of first enrolment
01/10/2006

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
Germany

Study participating centre

Robert- Koch- Str. 40
Gottingen
Germany
37073

Sponsor information

Organisation
Georg-August University of Gottingen (Georg-August-Unversitat Gottingen) (Germany)

Sponsor details
c/o Professor Dr Burkert Pieske
Robert- Koch- Str. 40
Gottingen
Germany
37073
-
pieske@med.uni-goettingen.de

Sponsor type
University/education

Website
http://www.uni-goettingen.de/en/sh/1.html

ROR
https://ror.org/01y9bpm73

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany) - Health Research, Competence Network on Heart Failure

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	18/10/2011	24/05/2019	Yes	No
Results article	results	01/05/2015	24/05/2019	Yes	No
Results article	results	01/02/2017	24/05/2019	Yes	No
Results article		29/04/2019	08/01/2024	Yes	No