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Optimization of bicycle Ergometer training

Submission date	Recruitment status	[ ] Prospectively registered
10/07/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/08/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/08/2006	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.refonet.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
03002

Study information

Scientific Title

Acronym
OpErgo

Study objectives
In accordance with the two training methods there are different training recommendations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commitee of the Ärztekammer Nordrhein approved on the 31st August 2005 (reference number: 2005255).

Study design
Randomised, prospective, controlled trial.

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
Coronary heart disease

Interventions
Group one exercises with an intensity of 60% of the symptom-limited performance regulated by heart rate.
Group two exercises metabolically regulated with an intenstity analogous to 60% of the intensity connected with 3 mmol/l lactate in capillary blood.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
In accordance with the two training methods there are different training recommendations.

Secondary outcome measures
Training efficiency is enhanced by the intensity regulation based on metabolic parameters.

Overall study start date
01/11/2005

Completion date
31/10/2006

Eligibility

Key inclusion criteria
1. Angiographic proved coronary disease
2. Echocardiogram (ECG) proved normal or slightly limited systolic cardiac function
3. Angina pectoris or acute coronary syndrome more than or equal to ten days before joining the research project
4. Sinus rhythm

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
340

Key exclusion criteria
1. Acute coronary syndrome less than ten days before joining the research project
2. Moderate to severe limited sysolic cardiac function
3. Aorto-coronary bypass operation more than or equal to three months before joining the research project
4. Atrial fibrillations or therapy relevant ventricular arrythmia
5. Clinically limiting peripheral arterial disease
6. Present hypertrophic obstructive cardiac myopathy
7. Non-regulatable arterial hypertonia
8. Haemodynamically relevant cardiac valvular defect
9. Pericarditis, myocarditis and lung embolic more than or equal to six months before joining the research project
10. Limiting orthopaedic secondary disorders
11. Consuming and intercurrent diseases
12. Renal insufficiency (Creatinine > 2.0 mg/dl)
13. Anaemia (haemoglobin [Hb] < 12g/dl)
14. Severe chronic obstructive pulmonary disease (Forced Expiratory Volume in one second

[FEV1] < 35%)
15. Respiratory global insufficiency
16. Implantable Cardioverter Defibrillator (ICD) implantation

Date of first enrolment
01/11/2005

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Germany

Study participating centre
Roderbirken 1
Leichlingen
Germany
42799

Sponsor information

Organisation
Refonet (Germany)

Sponsor details
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Sponsor type
Not defined

Website
http://www.refonet.de

ROR
https://ror.org/04yeh2x21

Funder(s)

Funder type
Industry

Funder Name
Refonet

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