

# Optimization of bicycle Ergometer training

<b>Submission date</b> 10/07/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/08/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/08/2006	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

### Contact name

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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 Committee 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 intensity 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 systolic 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 arrhythmia
5. Clinically limiting peripheral arterial disease
6. Present hypertrophic obstructive cardiac myopathy
7. Non-regulatable arterial hypertension
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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service@refonet.de

**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