

# Secondary prevention for inpatients with coronary artery disease in rehabilitation and conceptual aftercare

<b>Submission date</b> 13/02/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/03/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/09/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.refonet.de>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Wolfgang Mayer-Berger

### Contact details

Roderbirken 1  
Leichlingen  
Germany  
42799  
+49 (0)217 5824010  
[wolfgang.mayer-berger@klinik-roderbirken.de](mailto:wolfgang.mayer-berger@klinik-roderbirken.de)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Acronym

Sekona

## Study objectives

Structured aftercare leads to:

1. Reduction in the long-term risk of the occurrence of any cardiac event
2. Slowing down of atherosclerosis
3. Quality of life improvement
4. Reduction in the direct and indirect costs involved, including delayed pension claims

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics Committee of the Physicians Chamber, North Rhein, Dusseldorf, Germany 22/07/2004, reference number 2004093

## Study design

Prospective randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Prevention

## Participant information sheet

## Health condition(s) or problem(s) studied

Coronary heart disease

## Interventions

Secondary cardiac prevention program with reminders and follow-up education after remission for up to 18 months versus usual care

## Intervention Type

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Reduction of the 10-year risk of the occurrence of any cardiac event

## **Secondary outcome measures**

1. Regression or slower progression of atherosclerosis as measured by the carotidal intima-media-thickness
2. Quality of life improvement
3. Reduction in the direct and indirect costs involved, including delayed pension claims

## **Overall study start date**

01/09/2004

## **Completion date**

01/03/2007

# **Eligibility**

## **Key inclusion criteria**

1. Membership of the German Pension Insurance Fund, Rhineland
2. Younger than 58 years old
3. Overt coronary heart disease
4. Participants must sign an informed consent form

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

600

## **Key exclusion criteria**

1. Heart failure according to the New York Heart Association (NYHA) classification III or IV
2. Any prognostic limiting illness
3. Limiting pulmonary disease (forced expiratory volume in one second [FEV 1] lower than 35%)
4. Cognitive problems or problems with understanding
5. Low mobility

## **Date of first enrolment**

01/09/2004

**Date of final enrolment**

01/03/2007

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

**Roderbirken 1**

Leichlingen

Germany

42799

## **Sponsor information**

**Organisation**

Refonet (Germany)

**Sponsor details**

Burgweg 3

Bad Neuenahr-Ahrweiler

Germany

53445

+49 (0)264 190620

service@refonet.de

**Sponsor type**

Research organisation

**Website**

<http://www.refonet.de>

**ROR**

<https://ror.org/04yeh2x21>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Refonet (Germany)

## 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?
<a href="#">Results article</a>	results	01/02/2014		Yes	No