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

Submission date 13/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/03/2006	**Overall study status** Completed	
Last Edited 30/09/2014	**Condition category** Circulatory System	

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
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 Hearth 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
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Sponsor type
Research organisation

Website
http://www.refonet.de

ROR
https://ror.org/04yeh2x21

Funder(s)

Funder type
Research organisation

Funder Name

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	01/02/2014		Yes	No