Effects of patient-centered modular secondary prevention in people with acute coronary syndrome

Submission date Recruitment status Prospectively registered 24/01/2006 No longer recruiting [X] Protocol Statistical analysis plan Overall study status Registration date 24/01/2006 Completed [X] Results [] Individual participant data Last Edited Condition category Circulatory System 02/11/2022

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Julie Hila

Contact details

10/1-3 Funda Pl Brookvale Sydney NSW Australia 2100

Additional identifiers

Protocol serial number G03S1204

Study information

Scientific Title

Effects of patient-centered modular secondary prevention in people with acute coronary syndrome

Study objectives

This study aims to test the effect of modular secondary prevention on total blood cholesterol, heart disease risk factors and knowledge in persons who have had an acute coronary syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Central Sydney Area Health Services Human Research and Ethics Committee (CRGH) on 21st May 2003 (ref: CH/62/6/2003-021).

Study design

Single blinded, randomised controlled trial with three groups

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Coronary heart disease and acute coronary syndrome

Interventions

Intervention group will participate in modular prevention including individual risk factor assessment, goal setting and coaching. Control group will continue conventional care by their general practitioner. The standard cardiac rehabilitation group will participate in hospital-based cardiac rehabilitation including six weeks of group exercise and education.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Proportion of participants with total blood cholesterol less than 4.5 mmol/l.

Key secondary outcome(s))

Proportion of participants achieving nationally recommended targets for heart disease risk factors, absolute heart disease risk on the lipid risk score and risk factor knowledge

Completion date

01/07/2006

Eligibility

Key inclusion criteria

- 1. Acute coronary syndrome within 12 months of assessment
- 2. Refusal of invitation to participate in cardiac rehabilitation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

144

Key exclusion criteria

Diagnosis of uncontrolled cardiomyopathy, aortic stenosis, arrhythmia, dementia or a terminal illness such as end-stage renal failure

Date of first enrolment

01/01/2004

Date of final enrolment

01/07/2006

Locations

Countries of recruitment

Australia

Study participating centre 10/1-3 Funda Pl Sydney NSW

Australia

2100

Sponsor information

Organisation

National Heart Foundation of Australia

ROR

https://ror.org/039d9wr27

Funder(s)

Funder type

Charity

Funder Name

National Heart Foundation of Australia Grant-in-Aid (G03S1204) and a Postgraduate Clinical Research Scholarship for Julie Hila (PC03S1258).

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		01/03/2009		Yes	No
Protocol article		09/06/2006		Yes	No