

Randomised controlled trial to assess the efficacy of a comprehensive secondary prevention programme in primary care

Submission date 08/03/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 04/04/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/04/2008	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym

PREseAP

Study objectives

A comprehensive programme on secondary prevention of cardiovascular diseases in primary care reduces rehospitalisation and mortality, and improves quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Cardiovascular disease

Interventions

Health Centres (clusters) are randomised to intervention or control group.

Intervention group (comprehensive programme in secondary prevention led by well-trained registered nurses):

Patient education and counselling, optimisation of the treatments according to CVD prevention guidelines (drugs, diet, exercise). The number of scheduled visits will be 9 (every 4 months).

Control group:

Patients in the control group will be assigned to conventional care. Number of visits: two (baseline assessment and final visit at the end of the trial).

Follow-up period: 3 years

Endpoints: combined of cardiovascular disease mortality and cardiovascular disease morbidity (including revascularisation)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Combination of total mortality
2. Cardiovascular fatal events
3. Cardiovascular non-fatal events

Key secondary outcome(s)

1. Total mortality
2. Cardiovascular fatal events
3. Cardiovascular non-fatal events
4. Quality of life measured with the 36-item short form health survey (SF-36) instrument

Completion date

31/12/2007

Eligibility**Key inclusion criteria**

Patients are recruited from 42 primary health care centres from eight different regions of Spain (2100 patients are expected to be recruited).

Inclusion Criteria:

Males and females below 86 years, diagnosed with coronary heart disease (CHD), stroke or peripheral vascular disease in the last year.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients diagnosed with cardiovascular disease (CVD) before the year 2004
2. Unstable patients (post myocardial infarction [MI] angina of less than 28 days after discharge, ventricular arrhythmias in the last six months)
3. Subarachnoid haemorrhage, cerebral embolisms secondary to valve disease
4. Patients with concomitant serious chronic disease (cancer, chronic renal failure, etc.)
5. Patients with poor mental function or any other reason to expect that the patient may have difficulty in complying with the requirements of the study

Date of first enrolment

01/01/2005

Date of final enrolment

31/12/2007

Locations**Countries of recruitment**

Spain

Study participating centre**Unit of Research**

Barcelona

Spain

08025

Sponsor information

Organisation

Sardenya Primary Care Center (in collaboration with the Catalan Foundation Institute of Pharmacology) (Spain)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Carlos III Health Institute of the Spanish Ministry of Health and Consumption (Fondo de Investigaciones Sanitarias - Instituto de Salud Carlos III-Ministerio de Sanidad y Consumo) (Spain) (ref: PI031421)

Results and Publications

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	01/03/2008		Yes	No