ISRCTN18578323 https://doi.org/10.1186/ISRCTN18578323

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Carlos Brotons

Contact details
Unit of Research
Sardenya Primary Health Care Center
Sardenya 466
Barcelona
Spain
08025
+34 935 67 43 80
cbrotons@eapsardenya.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design
Randomised 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
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 assessmenta 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 measure
1. Combination of total mortality
2. Cardiovascular fatal events
3. Cardiovascular non-fatal events

Secondary outcome measures
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

Overall study start date
01/01/2005

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

Age group
Adult

Sex
Both

Target number of participants
2100

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)

Sponsor details
Sardenya 466
Barcelona
Spain
08025
+34 935 67 43 80
cbrotons@eapsardenya.net

Sponsor type
Hospital/treatment centre

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

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	01/03/2008		Yes	No