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A secondary prevention programme of ischaemic heart disease in the elderly

Submission date
16/09/2016

Recruitment status
No longer recruiting

Registration date
01/10/2016

Overall study status
Completed

Last Edited
08/11/2023

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Coronary artery disease (CAD), also known as ischemic heart disease, is one of the leading causes of death worldwide. CAD develops because of the build-up of fatty deposits (plaque) on the walls of the coronary arteries (the arteries that supply the heart with oxygen-rich blood). It is the leading cause of death in older adults, and its consequences are a major source of long-term disability, loss of independence and impaired quality of life. In patients with CAD, it is important to control cardiovascular risk factors (factors that put a person at risk of having a cardiovascular event, such as a stroke or heart attack) and improve the lifestyle in order to reduce the risk of a relapse. There are lots of studies in younger patients, but in older patients there is a lack of data. The aim of this study is to look at older patients with CAD to compare two different ways for achieving the control of cardiovascular risk factors and improving lifestyle during the year after discharge.

Who can participate?
Patients aged 70 years and over who have been diagnosed with CAD and admitted to the Cardiology Department of the Bellvitge University Hospital.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive lifestyle recommendations (such as how to get more exercise and follow a Mediterranean diet) and changes in their drug treatment when needed to help lower their cardiovascular risk factors, as well as receiving standard care. Those in the second group receive standard care which involves being given lifestyle recommendations and drug treatment prescribed by their general practitioner and cardiologist. At the start of the study and after 12 months, participants in both groups complete a number of questionnaires and physical tests to see if their cardiovascular risk factors have changed. In addition, participants are followed up 3 years later to find out how many are still living.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
Vascular Risk Unit of Bellvitge Hospital (Spain_

When is the study starting and how long is it expected to run for?
September 2004 to June 2014

Who is funding the study?
Bellvitge University Hospital-IDIBELL (Spain)

Who is the main contact?
Dr Elisenda Marcos Forniol
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
S/N

Study information

Scientific Title
Is a secondary prevention program compared with usual care effective to improve the achievement of cardiovascular risk factors goals in patients ≥ 70 years old with recent acute coronary syndrome?

Study objectives
The aim of this study is to ascertain the effects of a secondary prevention programme of cardiovascular disease on the control of CVRF, lifestyle, quality of life and functionality in elderly patients with a recent coronary event.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of Bellvitge University Hospital, 28/11/2011, ref: PR292/11

Study design
Open randomized intervention study with parallel groups

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Coronary heart disease

Interventions
Patients will be recruited before hospital discharge, and are randomized to an intervention or control group within the next three months. Patients will be randomised by a balanced randomised block method.

Intervention group: Participants will attend appointments at baseline, 3, 6, 9 and 12 months. During this time, participants continue to will receive their usual care through their family physicians and cardiologist. At the appointments at baseline and 12 months, participants are assessed by a physician, a nurse and a nutritionist. At the appointments a nurse takes the blood pressure, heart rate, weight and height (only at baseline), and participants will complete the Short Physical Performance Battery (SPPB) and the Yesavage questionnaire. The nurse will also give physical activity counselling to improve lifestyle. The nutritionist will perform a food-frequency questionnaire and the Short Form 36 Health Survey (SF-36). Furthermore, she will give dietary recommendations to improve adherence to the Mediterranean diet. The physician will conduct a medical history, a physical examination and revise the blood test performed the week before. They will also indicate changes in drug treatment when needed to improve the cardiovascular risk factors goals for the secondary prevention of cardiovascular disease. At the appointments at 3, 6 and 9 months, patients will be assessed by the nurse and the physician. A week before a blood test will be performed. The nurse will take the blood pressure, heart rate and weight. The physician will assess clinical, physical and blood test areas in order to make modifications to the treatment if needed, and remind patients of the initial physical activity, diet and lifestyle recommendations.

Control group: Participants will receive their usual care through their family physicians and cardiologist, that is the normal procedure after a discharge from hosptial.
At baseline and 12 months, participants will attend an appointment at which they are assessed by a physician, a nurse and a nutritionist in order to collect the data. At the appointments a

nurse will take the blood pressure, heart rate, weight and height (only at baseline), and participants will complete the Short Physical Performance Battery (SPPB) and the Yesavage questionnaire. The nutritionist will perform a food-frequency questionnaire and the Short Form 36 Health Survey (SF-36). The physician will conduct a medical history, a physical examination and revise the blood test performed the week before.

Three years after the intervention finished, mortality was evaluated.

Intervention Type
Mixed

Primary outcome(s)
1. Blood pressure is measured during patient interviews using a digital sphygmomanometer at baseline and 12 months
2. LDL cholesterol is measured by a fasting blood test performed the week before the appointments at baseline and 12 months
3. Smoking status is assessed during patient interviews at baseline and 12 months
4. Body mass index is caclulated during patient interview using the weight and height measurements at baseline and 12 months
5. Physical activity is measured using the Metabolic Equivalent of Task (MET) h/wk during patient interviews at baseline and 12 months
6. Glycosylated haemoglobin is measured by a fasting blood test performed the week before the appointments at baseline and 12 months

Key secondary outcome(s))
1. Adherence to the Meditrranean Diet is measured with a nine-item score (Martínez- González, 2004) calculated from the food-frequency questionnaire performed during patient interview at baseline and 12 months
2. Quality of life is measured using the Short Form 36 Health Survey at baseline and 12 months
3. Physical performance is measured using the Short Physical Performance Battery (SPPB) during patient interviews at baseline and 12 months
4. Mortality rate is assessed three years after the 12-month follow-up using clinical records and the National Death Index

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Consecutive patients ≥70 years old
2. Diagnosed with acute coronary syndrome
3. Admitted to the Cardiology Department of the Bellvitge University Hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Senior

Lower age limit
70 years

Sex
All

Total final enrolment
127

Key exclusion criteria
1. Diagnosis of cancer
2. Functional dependence (Barthel Index score ≤75)
3. Cognitive impairment (Pfeiffer's Short Portable Mental State Questionnaire >5 mistakes)
4. Difficulties attending appointments
5. Very low life expectancy

Date of first enrolment
01/09/2004

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
Spain

Study participating centre
Bellvitge University Hospital-IDIBELL
Vascular Risk Unit
Internal Medicine Department
Feixa Llarga s/n
Hospitalet de Llobregat
Barcelona
Spain
08907

Sponsor information

Organisation
Bellvitge University Hospital-IDIBELL

ROR

https://ror.org/00epner96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bellvitge University Hospital-IDIBELL

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Elisenda Marcos Forniol (elimarcos@gmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2018	08/11/2023	Yes	No
Basic results		27/09/2016	05/10/2016	No	No
Participant information sheet		27/09/2016	05/10/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes