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Impact of comprehensive and intensive treatment of risk factors concerning cardiovascular mortality in secondary prevention: MIRVAS study

Submission date
26/12/2008

Recruitment status
No longer recruiting

Registration date
19/02/2009

Overall study status
Completed

Last Edited
19/02/2009

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
N/A

Study information

Scientific Title

Impact of comprehensive and intensive treatment of risk factors concerning cardiovascular mortality in secondary prevention: MIRVAS study - a randomised controlled trial

Acronym
MIRVAS

Study objectives
Patients with coronary and cerebrovascular disease receiving secondary prevention care through a comprehensive and intensive cardiovascular risk factors control can reduce cardiovascular morbidity and mortality at three years after the cardiovascular event.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics and Research Committee of La Princesa University Hospital (Hospital Universitario de La Princesa). Formal written approval was granted on 01/07/2005 (ref: PI-77) (Initial approval was given orally in 2002).

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Secondary prevention of cardiovascular disease

Interventions
The MIRVAS study is a randomised controlled trial conducted at La Princesa University Hospital. Patients were included in the study between September 2002 and February 2004.

On the day of admission to the hospital, the patients allocated to the intervention group received a health education talk by a trained nurse, who informed them of the meaning of their illness and the importance of carrying out the treatment properly. Later visits were scheduled at 2, 5, 12, 24 and 36 months after the acute episode with more reviews being able to be carried out if deemed appropriate. In addition, patients could see other specialists connected with their cardiovascular disease. The talk made during each visit consisted of a speech by a nurse (health education, change in lifestyle, assessing treatment adherence) and a medical assessment (clinical evaluation and modification of treatment if appropriate).

The patients in the control group received the routine follow-up in the cardiology or neurology consultations, and/or in primary care. They had annual appointments and their lifestyle habits, drug treatment they received, degree of control of the different cardiovascular risk factors (CVRF) and the presence or absence of symptoms, visits to the emergency ward and/or hospital visits for any reason were all recorded.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The following were assessed at three-year follow-up:
1. Cardiovascular mortality and cardiovascular morbimortality, which included the following events: 1.1. Cardiovascular death
1.2. Acute coronary syndrome with or without ST-segment elevation
1.3. Acute stroke (ischaemic or haemorrhagic)
1.4. Revascularisation in any area
1.5. Amputation as a result of peripheral ischaemia
2. Admittance due to heart failure
3. Control of risk factors

All episodes were understood as such if they had a clinical report to back them up. The assessments were carried out by an unblinded member of the research group.

Key secondary outcome(s))
The following were assessed at 1 and 3 years:
1. Percentage of patients who reached the optimal control of each risk factor
2. Percentage of pharmacological interventions recommended by international guidelines for secondary prevention of cardiovascular risk received in each arm

Completion date
01/09/2006

Eligibility

Key inclusion criteria
1. Both males and females, from 18 to 80 years old
2. Patients admitted to the hospital for acute coronary syndrome (with or without ST-segment elevation) or an ischaemic stroke

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Refusal or inability to participate in the follow-up (displaced patients or with reduced mobility)
2. Life expectancy of less than 12 months
3. Severe cognitive deterioration

Date of first enrolment
01/09/2002

Date of final enrolment
01/09/2006

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario de La Princesa
Madrid
Spain
28006

Sponsor information

Organisation
La Princesa University Hospital (Hospital Universitario de La Princesa) (Spain)

ROR
https://ror.org/03cg5md32

Funder(s)

Funder type
University/education

Funder Name
La Princesa University Hospital (Hospital Universitario de La Princesa), Biomedical Research Foundation (Fundación de Investigación Biomédioca) (Spain)

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	14/07/2007		Yes	No
Results article	results	01/03/2008		Yes	No