

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

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Registration date 19/02/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/02/2009	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/09/2002

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

247

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)

Sponsor details

c/o Dr Carmen Suarez
Diego de Leon 62
Madrid
Spain
28006

Sponsor type

Hospital/treatment centre

Website

http://www.madrid.org/cs/Satellite?pagename=HospitalLaPrincesa/Page/HPRI_home

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 Biomédica) (Spain)

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