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Multi-center cluster-randomised clinical trial to evaluate the efficacy of an intervention to improve anti-hypertensive medication adherence among patients with uncontrolled hypertension and high cardiovascular risk

Submission date 24/08/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/10/2004	**Overall study status** Completed	
Last Edited 02/12/2010	**Condition category** Circulatory System	

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

Acronym
COM 99

Study objectives
Added as of 01/12/2008:
The proposed study intervention to improve adherence to antihypertensive medication will improve both adherence to antihypertensive medication and the degree of blood pressure control. The better blood pressure control in the intervention group will result in a reduction of cardiovascular events.

Please note that, as of 01/12/2008, the start and end dates of this trial have been updated from 10/04/2000 and 05/05/2002 to 01/01/2000 and 01/12/2005, respectively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the Hospital General de Vic (Spain), approved on 02/06/1999.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Arterial hypertension

Interventions
Usual clinical practice will be continued in patients assigned to the control group. The intervention to improve adherence to antihypertensive medications in the treatment group will include multi-level components (behavioral, cognitive, and social support). The clinical guidelines published by the World Health Organization (WHO) and the International Society of Hypertension (ISH) will be used to classify patients by their cardiovascular risk. The trial will be actively monitored to perform quality data assurance as well as external auditing.
Outcomes: Adherence to medications will be measured in both the control and intervention group using an electronically monitored pill container (EDEM®), which registers the date and time a pill is removed from the container. Blood pressure will be registered at each visit with a validated semiautomatic
sphygmomanometer (OMRON 705-CP). Primary outcomes will include blood pressure, adherence levels, and cardiovascular morbidity and mortality. Expected follow-up time is 5 years.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Mean SBP and DBP values obtained during office visit (measured at each visit with a semiautomatic sphygmomanometer (OMRON 705-CP). Main analysis will include blood pressure data until visit 3 (6 months).

Key secondary outcome(s))
1. Medication adherence according to MEMS (medication event monitoring system) device results. Medication adherence data will include information on the first 6 months (visit 3). Apart from recording the date and time each time the container is opened, the information from the electronic device may be downloaded to a computer for further statistical analysis.
2. Time elapsed until the first cardiovascular morbidity or mortality event during follow-up (expected follow-up duration: 5 years).
2.1. Fatal events ascribable to cardiovascular pathology. the following will be included: sudden heart failure; fatal myocardial infarction; death during/post percutaneous transluminal coronary angioplasty (PTCA) or aortocoronary bypass; death due to congestive heart failure; fatal CVA.
2.2. Non-fatal events ascribable to cardiovascular pathology. the following will be included: debutant congestive heart failure requiring hospitalization or chronic congestive heart failure requiring hospitalization; non-fatal acute myocardial infarction, as verified by a ST-segment peak in the ECG and/or typical enzyme pattern; emergency thrombolytic treatment/fibrinolytic treatment and/or emergency PTCA/aortocoronary bypass to prevent extensive myocardial infarction, as verified by a ST-segment peak in the ECG and/or typical enzyme pattern; CVA verified by CAT or hospital recordings; angina diagnosed with positive treadmill test results; routine PTCA/aortocoronary bypass; unstable angina requiring hospitalization; silent myocardial infarction detected during the study and not present in the ECGs prior to the beginning of the study; terminal renal insufficiency, impaired renal function.

Completion date
01/12/2005

Eligibility

Key inclusion criteria
900 patients, aged 50 or older, presenting non-controlled systolic and/or diastolic hypertension, elevated cardiovascular risk (ten-year probability of a cardiovascular event ≥30%).
90 physicians from hospitals and primary care centers will be randomly allocated to the intervention or control group.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
1. Participation in any investigational clinical trial within the past 3 months.
2. Incapacity or unwillingness to sign the informed consent.

Date of first enrolment
01/01/2000

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
Spain

United States of America

Study participating centre
Center for Health Services Research - Henry Ford Health System
Detroit
United States of America
MI 48202

Sponsor information

Organisation
Osona Foundation for Research and Health Education (Fundació dOsona per a la Recerca i l Educació Sanitàries [FORES]) (Spain)

Funder(s)

Funder type
Government

Funder Name
Instituto de Salud Carlos III -Fondo de Investigación Sanitaria (Spanish Ministry of Health) (FIS00/0045-01 and FIS00/0045-02)

Funder Name
Catalan Agency for Health Technology Assessment and Research (AATM 02/24/98)

Funder Name
Novartis (COM99)

Alternative Name(s)
Novartis AG, Novartis International AG

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Funder Name
Almirall Prodesfarma (COM99)

Funder Name
Aventis (COM99)

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	21/09/2010		Yes	No