European survey of cardiovascular disease prevention and diabetes (EuroAspire) - IV

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON41357

Source
ToetsingOnline

Brief title
EuroAspire-IV

Condition

- Coronary artery disorders

Synonym
chestpain, coronary heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Astra Zeneca, Servier, Roche en Novartis sponsoren deze survey via de European Society of Cardiology

(ondersteuning centrale organisatie en Corelab) . Deelnemende centra ontvangen geen vergoeding vanuit de ESC (geen additionele info bekend over sponsoren van ESC)

Intervention

Keyword: cardiovascular disease, diabetes, prevention, survey

Outcome measures

Primary outcome

To evaluate the proportions of hospital coronary patients and high risk individuals in primary care achieving European lifestyle, risk factors and therapeutic targets for cardiovascular disease prevention.

The evaluate the management of risk in terms of lifestyle intervention and the use of drug therapies in relation to the lifestyle and therapeutic goals defined in the Vth European guidelines on cardiovascular disease prevention (2012).

Secondary outcome

To evaluate cardiovascular events (non-fatal coronary and cardiovascular events, including revascularisation and hospitalisations, and cardiovascular/total mortality)

Study description

Background summary

The main objectives of cardiovascular disease (CVD) prevention are to reduce morbidity and mortality, improve quality of life, and increase the chances of a longer life expectancy. A wealth of scientific evidence from observational studies and randomised controlled trials now supports interventions in relation to lifestyle (smoking, diet and exercise), the treatment of hypertension,

hyperlipidaemia, and diabetes, and the selective use of prophylactic drug therapies (anti-platelets, betablockers, ACE inhibitors/ARBs, lipid modifying drugs and antithrombotics). All of these measures can reduce morbidity and mortality in those with established coronary disease and can also help to reduce the risk of developing this disease.
The European Society of Cardiology together with other partner Societies has engaged in a comprehensive programme of CVD prevention in clinical practice since 1992. Guidelines on this important topic have been developed and updated at regular intervals over the last 15 years: 1994, 1998, 2003, 2007 and the Vth version will be published in 2012. The aim of the Joint European Societies Guidelines on cardiovascular disease prevention is to improve the practice of preventive cardiology by encouraging the development of national guidance on cardiovascular disease prevention and its communication, implementation and evaluation through national societies in each country. Patients with coronary or other atherosclerotic cardiovascular disease, and those at high risk of developing CVD, have been defined as the highest clinical priorities for prevention.
The results of EUROASPIRE I, II and III surveys demonstrated a high prevalence of unhealthy lifestyles, modifiable risk factors and inadequate use of drug therapies to achieve blood pressure and lipid goals in patients with established CHD and people at high risk of developing cardiovascular disease, with wide variations in medical practice between countries. The 2007 Joint European Societies* Guidelines defined the lifestyle and risk factor goals for patients with established CHD and people at high CVD risk as follows: stop smoking, make healthy food choices and be physically active; a body mass index (BMI) <25 kg/m2; blood pressure <130/80 mm Hg, total cholesterol <4.0 mmol/L, LDL-cholesterol <2.0 mmol/L, if feasible, and appropriate use of cardioprotective drug therapies.
A fourth EUROASPIRE survey is now proposed under the auspices of the European Society of Cardiology, EuroObservational Research Programme, and led by the European Association for Cardiovascular Prevention and Rehabilitation. This fourth survey will merge with the EuroHeart Survey on Diabetes Mellitus and incorporate an assessment of dysgycaemia (impaired fasting glycaemia {IFG}, impaired glucose tolerance {IGT} and new diabetes) in all patients. As in the previous EUROASPIRE surveys this survey will focus on hospital patients with coronary heart disease, with and without diabetes mellitus, and apparently healthy individuals in primary care at high risk of developing cardiovascular disease including those with diabetes. The survey will be undertaken in 2012-2013.

Study objective

The objectives of EUROASPIRE IV are:
1. To determine in patients with established CHD (acute myocardial infarction and ischaemia and patients following revascularisation by angioplasty or coronary artery surgery) and in high multifactorial risk individuals whether the European guidelines on cardiovascular disease prevention are being

followed.
2. To determine whether the practice of preventive cardiology in patients with established coronary disease in EUROASPIRE IV has improved by comparison with those hospital centres which took part in EUROASPIRE I, II and III and whether the practice of preventive cardiology in patients in primary care at high risk of developing CVD in EUROASPIRE IV has improved by comparison with those centres which took part in EUROASPIRE III.
3. To compare diagnostic and therapeutic strategies in patients with established coronary disease, and those at high multifactorial risk of developing CVD, in relation to glucose metabolism (impaired fasting glycaemia, impaired glucose tolerance and diabetes).
4. To compare diagnostic and therapeutic strategies in patients with established coronary disease, and those at high multifactorial risk of developing CVD, in relation to chronic kidney disease (CKD).
5. To follow up patients from EUROASPIRE I, II and III for total and cause-specific mortality and morbidity to determine the relationships between risk factors measured at interview and event-free survival.
6. To identify strategies for improving preventive care, based on the EUROASPIRE survey results from hospital and general practice, and to make recommendations to the European Association for Cardiovascular Prevention and Rehabilitation.

Study design

Cross-sectional survey

Study burden and risks

The burden concerns the visit to the outpatients, filling out questionnaires, and blood tests (OGTT incl in non-diabetic)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- *18 years and < 80
- first or recurrent clinical diagnosis or treatments for coronary heart disease (see below) will be retrospectively identified from diagnostic registers, hospital discharge lists or other sources
- the starting date for identification will be not less than 6 months and not more than 3 years prior to the expected date of interview.
- Patients may fulfil more than one of the following diagnostic criteria:
* Elective or emergency coronary artery by-pass graft (CABG) operation (this includes emergency
CABG for AMI).
* Elective or emergency percutaneous transluminal coronary angioplasty (PCI) (this includes primary
PCI for AMI).
* Acute myocardial infarction (ST elevation and Non ST elevation MI)
* Acute myocardial ischaemia but no evidence of infarction (Troponin negative)

Exclusion criteria

Patients admitted to hospital from outside the geographical area

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2012
Enrollment:	715
Type:	Actual

Ethics review

Approved WMO Date:	25-04-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-04-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL39266.078.12