

EUROPEAN SURVEY OF CARDIOVASCULAR DISEASE PREVENTION, DIABETES AND CHRONIC KIDNEY DISEASE, EUROASPIRE VI

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Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57093

Source

ToetsingOnline

Brief title

EUROASPIRE VI

Condition

- Coronary artery disorders

Synonym

coronary heart disease, ischemic heart disease

Research involving

Human

Sponsors and support

Primary sponsor: European Society of Cardiology

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2-06-2025

Source(s) of monetary or material Support: Ministerie van OC&W, Nederlandse Hartstichting ,NovoNordisk

Intervention

Keyword: Cardiovascular disease, Prevention, Risk factor, Treatment

Outcome measures

Primary outcome

To evaluate the proportion of patients achieving European lifestyle, risk factors and therapeutic targets for cardiovascular disease prevention.

Secondary outcome

Not applicable

Study description

Background summary

The results of EUROASPIRE I, II, III, IV and V 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 CVD risk, with wide variations in medical practice between countries. Based on the EUROASPIRE methodology, an INTERASPIRE survey is now being conducted in partnership with the World Heart Federation, the European Society of Cardiology EuroObservational Research Programme and other continental scientific societies encompassing all five WHO regions outside Europe.

This sixth EUROASPIRE survey will investigate the cardiometabolic and renal continuum in both secondary and primary cardiovascular disease prevention in 2023-2025 under the auspices of the European Society of Cardiology, Global Registries And Surveys Programme (GRASP). As in the previous EUROASPIRE surveys this survey will be focused on hospital patients with CHD, with and without diabetes mellitus, and apparently healthy individuals in primary care at high risk (hypertension, dyslipidaemia, diabetes) of developing CVD.

This sixth survey will give a unique European picture of preventive action by cardiologists, other specialists and primary care physicians looking after patients with CHD, individuals at high CVD risk and all those with hypertension, dyslipidaemia (including familial hypercholesterolaemia),

diabetes and dysglycaemia and chronic kidney disease (CKD) and determine whether the European guidelines on CVD prevention, hypertension, lipids, diabetes and chronic kidney disease are being followed.

Study objective

The objectives of EUROASPIRE VI survey of CVD prevention and diabetes are:

1. To determine in patients with established CHD (CHD = acute myocardial infarction (AMI) and acute ischaemia (unstable angina) and patients following revascularisation by a percutaneous coronary intervention (PCI) or coronary artery by-pass graft surgery (CABG)) and in patients at high risk of developing CVD risk, whether the 2021 European guidelines on CVD prevention are being followed.
2. To compare diagnostic and therapeutic strategies in CHD and high-risk patients for hypertension to determine whether the 2018 European guidelines on hypertension are being followed.
3. To compare diagnostic and therapeutic strategies in CHD and high-risk patients for glucose metabolism (impaired fasting glycaemia, impaired glucose tolerance and diabetes) to determine whether the 2019 European guidelines on diabetes, prediabetes and CVD are being followed.
4. To compare diagnostic and therapeutic strategies in CHD and high-risk patients, including those with familial hypercholesterolaemia, for their lipid (total cholesterol, HDL-cholesterol, triglycerides and Lp(a) management to determine whether the 2019 lipid guidelines are being followed.
5. To compare diagnostic and therapeutic strategies in CHD and high-risk patients for chronic kidney disease (either albuminuria and/or reduced kidney function defined as an eGFR <60 ml/min/1.73 m²) to determine whether the CKD guidelines (ADA/EASD, KDIGO) are being followed.
6. To determine whether organ-protective medications, that protect the heart and the kidneys as recommended in the guidelines, are prescribed (and up-titrated to the correct doses as appropriate) in every day clinical practice.
7. To determine whether the preventive strategies in patients with established CHD in EUROASPIRE VI has improved by comparison with those hospital centres which took part in previous EUROASPIRE surveys and whether the practice of preventive cardiology in patients in primary care at high CVD risk in EUROASPIRE VI has improved by comparison with those centres which took part in EUROASPIRE III, IV and V.
8. To follow-up all coronary patients from EUROASPIRE VI one and five years after the interview for hospitalisations, cardiovascular procedures, cardiovascular events and cardiovascular and all cause mortality to determine the impact of risk factors for CVD and their management and event- free survival.
9. 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 Preventive Cardiology.

Study design

The ESC EUROASPIRE VI registry is an international multicentre, observational, cross-sectional study of patients presenting to hospital and primary care centres in countries whose National Cardiac Societies are ESC members.

Study burden and risks

The burden comprises a visit to the out-patients clinic, filling out questionnaires (< 5 minutes), a blood pressure measurement and a single blood draw.

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

- Patients having signed an informed Consent
- Patients aged from 18 years old at the time of identification
- At least six and at most 24 months elapsed between the index event (the recruiting diagnostic or treatment criteria below) and the date of interview
- Patients meeting the recruiting diagnostic or treatment criteria:
 - Coronary patients: Acute coronary events (acute coronary syndrome {STEMI or NSTEMI}, unstable angina) or an emergency or elective revascularisation for coronary artery disease (CABG, PCI)

Exclusion criteria

- Patients living outside defined geographical areas
- Patients admitted to hospital from outside the geographical area or under the care of cardiologists in hospitals that do not participate in EUROASPIRE VI

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-11-2024

Enrollment: 800

Type: Anticipated

Medical products/devices used

Registration: No

Ethics review

Approved WMO

Date: 06-11-2024

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 15-01-2025

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

CCMO

ID

NL87071.078.24