ISRCTN71715857 https://doi.org/10.1186/ISRCTN71715857

EUROACTION - A European wide effort to raise the standards of preventive cardiology

Submission date	Recruitment status	[_] Prospectively registered
05/07/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/04/2022	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.escardio.org/Policy/Pages/EuroAction.aspx

Contact information

Type(s)
Scientific

Contact name
Prof David Wood

Contact details
5th Floor Laboratory Block
Imperial College
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF
+44 (0)20 8846 1258
d.wood@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
EUROACTION - A European wide effort to raise the standards of preventive cardiology

Acronym
EUROACTION

Study objectives
The aim of the study is to raise standards of preventive cardiology in Europe by demonstrating that the recommended European lifestyle, risk factor and therapeutic goals in cardiovascular prevention are achievable and sustainable in everyday clinical practice.

EUROACTION is organised as a cluster randomised controlled intervention trial. In each of six countries a pair of general hospitals (12 in total) and a pair of general practices (12 in total) are recruited. Hospitals and general practices are randomised within pairs to receive the EUROACTION programme or to be monitored for usual care. The proportion of patients and family members achieving the European lifestyle, risk factor and therapeutic goals in the EUROACTION programme will be compared with usual care at one year.

On completion, the EUROACTION programme will be offered to national professional societies and heart foundations, as an evaluated practice model for preventive cardiology.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval not yet gained as of 12th September 2006.

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Coronary Heart Disease (CHD)

Interventions
EUROACTION brings together a multidisciplinary team, comprising cardiologists, general practitioners, specialist nurses, dieticians, and physiotherapists and physical activity specialists to show that the Guidelines can be followed and lifestyle, risk factor and therapeutic goals achieved.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Hospital arm:
1. Coronary patients: Proportions of patients achieving European and national lifestyle, risk factors and therapeutic targets for cardiovascular disease prevention:
1.1. Smoking habit (self reported, breath carbon monoxide (CO)
1.2. Diet/nutrition (self reported, food habit questionnaire, 24 hour recall with analysis)
1.3. Physical activity (self reported, step counter, incremental shuttle walk test, international physical activity questionnaire)
1.4. Overweight/obesity (Body Mass Index [BMI], waist circumference)
1.5. Diabetes (known/new, fasting and random plasma glucose, glycated haemoglobin (Hb A1c), Glucose Tolerance Test (GTT)
1.6. Blood pressure (automatic sphygmomanometer)
1.7. Total cholesterol, High-Density Lipoprotein (HDL) cholesterol, triglycerides, calculated Low-Density Lipoprotein (LDL) cholesterol)
1.8. Prophylactic drug therapies: nicotine replacement therapy, bupropion hydrochloride, antiobesity drugs, antiplatelets, beta-blockers, Angiotensin Converting Enzyme (ACE)-inhibitors, lipid-lowering drugs, anticoagulants, hypoglycaemic drugs
2. Partners and first-degree relatives of patients with premature coronary disease living in the same household: Proportions of partners and first degree relatives achieving European and national lifestyle, risk factors and therapeutic targets for cardiovascular disease prevention:
2.1. Smoking habit (self reported, breath CO)
2.2. Diet/nutrition (self reported, food habit questionnaire, 24 hour recall with analysis)
2.3. Physical activity (self reported, step counter, international physical activity questionnaire)
2.4. Overweight/obesity (BMI, waist circumference)
2.5. Diabetes (known/new, fasting and random plasma glucose, Hb A1c)
2.6. Blood pressure (automatic sphygmomanometer)
2.7. Total cholesterol, HDL cholesterol, triglycerides, calculated LDL cholesterol)
2.8. Prophylactic drug therapies: nicotine replacement therapy, bupropion hydrochloride, antiobesity drugs, antiplatelets, beta-blockers, ACE-inhibitors, lipid-lowering drugs, anticoagulants, hypoglycaemic drugs
3. First-degree relatives of patients with premature coronary disease not living in the same household: Proportions of first degree relatives achieving European and national lifestyle, risk factors and therapeutic targets for cardiovascular disease prevention:
3.1. Smoking habit (self reported)
3.2. Diet/nutrition (self reported)
3.3. Physical activity (self reported)
3.4. Overweight/obesity (BMI)

3.5. Diabetes (known/new, fasting and random plasma glucose)
3.6. Blood pressure
3.7. Total cholesterol, HDL cholesterol, triglycerides, calculated LDL cholesterol
3.8. Prophylactic drug therapies: nicotine replacement therapy, bupropion hydrochloride, antiobesity drugs, antiplatelets, beta-blockers, ACE-inhibitors, lipid-lowering drugs, anticoagulants, hypoglycaemic drugs

Primary Care:
1. High-risk individuals: Proportions of high risk individuals achieving European and national lifestyle, risk factors and therapeutic targets for cardiovascular disease prevention:
1.1. Smoking habit (self reported, breath CO)
1.2. Diet/nutrition (self reported, food habit questionnaire)
1.3. Physical activity (self reported, step counter, Chester step test)
1.4. Overweight/obesity (BMI, waist circumference)
1.5. Diabetes (known/new, fasting and random plasma glucose, HBA1c)
1.6. Blood pressure (automatic sphygmomanometer)
1.7. Total cholesterol, HDL cholesterol, triglycerides, calculated LDL cholesterol
1.8. Prophylactic drug therapies: antiplatelets, ACE-inhibitors, lipid-lowering drugs, hypoglycaemic drugs, nicotine replacement therapy, bupropion hydrochloride, antiobesity drugs
2. Partners of high-risk individuals living in the same household: Proportions of partners achieving European and national lifestyle, risk factors and therapeutic targets for cardiovascular disease prevention:
2.1. Smoking habit (self reported, breath CO)
2.2. Diet/nutrition (self reported, food habit questionnaire)
2.3. Physical activity (self reported, step counter)
2.4. Overweight/obesity (BMI, waist circumference)
2.5. Diabetes (known/new, fasting and random plasma glucose, HbA1c)
2.6. Blood pressure (automatic sphygmomanometer)
2.7. Total cholesterol, HDL cholesterol, triglycerides, calculated LDL cholesterol
2.8. Prophylactic drug therapies: nicotine replacement therapy, bupropion hydrochloride, antiobesity drugs, antiplatelets, ACE-inhibitors, lipid-lowering drugs, hypoglycaemic drugs

Secondary outcome measures

Hospital arm:
1. Coronary patients:
1.1. Psychosocial, depression (Hospital Anxiety and Depression (HAD) scale), compliance (self reported), health beliefs (health beliefs questionnaire), emotional state (global mood scale), illness perception (illness perception questionnaire), functional limitation (SF 36 questions)
1.2. Return to work
1.3. Service use
1.4. Health economics (EuroQoL questionnaire)
1.5. Cardiovascular events (recurrent nonfatal coronary and cardiovascular events and cardiovascular/total mortality)
2. Partners and first-degree relatives of patients with premature coronary disease living in the same household:
2.1. Psychosocial, depression (Hospital Anxiety and Depression (HAD) scale), compliance (self reported), health beliefs (health beliefs questionnaire), emotional state (global mood scale), illness perception (illness perception questionnaire), functional limitation (SF 36 questions)
2.2. Service use

2.3. Health economics (EuroQoL questionnaire)
2.4. Cardiovascular events (recurrent nonfatal coronary and cardiovascular events and cardiovascular/total mortality)

Primary Care:
1. High-risk individuals:
1.1. Psychosocial, depression (Hospital Anxiety and Depression (HAD) scale), health beliefs and views about heart disease (health beliefs questionnaire), risk perception (risk perception questionnaire), functional limitation (SF 36 questions)
1.2. Service use
1.3. Health economics (EuroQoL questionnaire)
1.4. Cardiovascular events (nonfatal coronary and cardiovascular events and cardiovascular/total mortality)
2. Partners of high-risk individuals living in the same household:
2.1. Psychosocial, depression (Hospital Anxiety and Depression (HAD) scale), health beliefs and views about heart disease (health beliefs questionnaire), risk perception (risk perception questionnaire), functional limitation (SF 36 questions)
2.2. Service use
2.3. Health economics (EuroQoL questionnaire)
2.4. Cardiovascular events (nonfatal coronary and cardiovascular events and cardiovascular/total mortality)

Overall study start date
08/04/2003

Completion date
30/04/2006

Eligibility

Key inclusion criteria
Hospital arm:
1. In- and out-hospital patients who meet the inclusion criteria and who agree to participate in the trial. Within each hospital (both intervention and usual care) all consecutive new patients with medical diagnosis of Coronary Heart Disease (CHD) (see below), men and women under 80 years of age, will be identified:
1.1. Acute coronary syndromes, unstable angina, non Q wave Myocardial Infarction (MI), Q wave MIb
1.2. Stable angina pectoris
2. Partners of patients living in the same household
3. First degree blood relatives of patients with premature CHD

Primary Care arm:
1. High risk individuals who meet the following inclusion criteria and who agree to participate in the trial. Men and women, 50 years of age or older, but less than 80 years, without history of coronary heart disease were identified in three categories as follows:
1.1. High multifactorial risk individuals: CVD risk more than or equal to 5% over ten years (now or projected to age 60 years), according to the HeartScore risk estimation system
1.2. Antihypertensive and/or lipid-lowering therapies initiated in the last year
1.3. New or known diabetes diagnosed in the last three years
2. Partners of high-risk individuals living in the same household

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10,000

Key exclusion criteria
Hospital arm:
1. Aged 80 years of age or older
2. Severe heart failure
3. Impaired cognitive function
4. Severe physical disability

Primary Care arm:
1. Under 50 and over 80 years of age
2. Mentally or physically incapable

Date of first enrolment
08/04/2003

Date of final enrolment
30/04/2006

Locations

Countries of recruitment
Denmark

England

France

Italy

Netherlands

Poland

Spain

Sweden

United Kingdom

Study participating centre
5th Floor Laboratory Block
London
United Kingdom
W6 8RF

Sponsor information

Organisation
European Society of Cardiology (France)

Sponsor details
European Heart House
2035 Route des Colles
Les Templiers - BP 179
F-06903 Sophia Antipolis Cedex
Nice
France
F-06903
+33 4 92 94 76 00
fheraud@escardio.org

Sponsor type
Other

Website
http://www.escardio.org

ROR
https://ror.org/02ahe3232

Funder(s)

Funder type
Industry

Funder Name
European Society of Cardiology (France)

Alternative Name(s)
ESC

Funding Body Type

Private sector organisation

Funding Body Subtype
International organizations

Location
France

Funder Name
AstraZeneca International - unconditional educational grant

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	14/06/2008		Yes	No
Other publications	cost-effectiveness	11/10/2012		Yes	No
Results article		31/03/2022	04/04/2022	Yes	No