Euroaction plus intensive smoking intervention (varenicline)

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A practical demonstration project in 5 European countries to show that intensive smoking intervention during a preventive cardiovascular risk management programme for patients with cardiovascular (CVD) or other atherosclerotic disease, asymptomatic...

Ethical review	-
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON38232

Source
ToetsingOnline

Brief title
Euroaction plus trial

Condition

- Cardiac disorders, signs and symptoms NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
prevention of cardiovascular disease, smoking cessation

Research involving
Human

Sponsors and support

Primary sponsor: Clinical Research Governance Office,Sir Alexander Fleming Building, Imperial College
Source(s) of monetary or material Support: Imperial College Londen en farmaceut Pfizer. Pfizer betaalt Imperial College 595.000 Engelse ponden voor het uitvoeren en

coordineren van het in de vijf genoemde landen en levert Varenicline gratis. Er is geen verdere inmenging van Pfizer in de onderzoeksopzet en in de verwerking en publicatie van de resultaten. Er is geen relatie tussen het Julius Centrum en Pfizer;noch tussen de uitvoerende onderzoekers in de Juliius Gezondheidscentra en Pfizer. Het Julius Centrum en de uitvoerende onderzoekers in de Julius Gezondheidscentra worden betaald door Imperial College. Hiervoor is een bedrag van 46.800 Euro afgesproken.,Pfizer

Intervention

Keyword: cardiovascular disease, prevention, smoking cessation, Varenicline

Outcome measures

Primary outcome

The primary outcome of the study will be the 7day point (period) prevalence of non-smoking at 16 weeks. The smoking cessation will be validated by breath CO < 10 ppm. Patients will be classified as non-smokers if they are not smoking in the week prior to their 16 week assessment even if they have relapsed several times in the intervening period. If they are smoking in that same week, and/or breath CO is raised, they will be classified as smokers. The primary outcome is the prevalence of non-smokers in intervention compared to usual care.

After more than one year after the study, the longterm effects of the intervention will be assessed by repeating the calculation of the non-smoking prevalence.

Secondary outcome

The secondary outcomes are:

(i) Number of smoking relapses in intervention.

(ii) Adverse effects

(iii) Proportions of patients achieving European and national lifestyle, risk factors and therapeutic targets for cardiovascular disease prevention:

a) smoking (self reported, breath carbon monoxide [CO]

b) diet/ nutrition (self reported, food habit questionnaire)

c) physical activity (self reported, step counter, Chester step test, DASI

physical activity questionnaire)

d) overweight/ obesity (body mass index (BMI), waist circumference)

e) diabetes (known/new, fasting and random plasma glucose, glycated haemoglobin

(Hb A1c) in patients with diabetes)

f) blood pressure

g) total cholesterol, high-density lipoprotein (HDL) cholesterol,

triglycerides, calculated low-density

lipoprotein (LDL) cholesterol)

h) smoking cessation drug therapies:

- Varenicline

- Nicotine replacement therapy

- Bupropion hydrochloride

i) cardioprotective drug therapies

iv) Patient reported outcomes: Hospital Anxiety and Depression Scale (HADS),

Quality of Life (EQ-5D).

After more than one year after the study, the longterm effecs on the outcomes

a, b, c (only DASI questionnaire), d, f, i, en iv.

Study description

Background summary

There is substantial evidence that professional lifestyle intervention on smoking, diet and physical activity together with control of cardiovascular risk factors can reduce the risk of cardiovascular disease. The recent Euroaction study showed in 2002 beneficial effects of a comprehensive cardiovascular risk management programme on achieving targets of European guidelines for cardiovascular disease prevention. However, a considerable proportion of coronary and high risk patients remained smokers at the end of the Euroaction programme, leaving considerable room for improvement. Therefore, a pragmatic trial is proposed to demonstrate whether Varenicline can achieve more effective smoking cessation in high risk patients within a comprehensive cardiovascular risk prevention programme.

Study objective

A practical demonstration project in 5 European countries to show that intensive smoking intervention during a preventive cardiovascular risk management programme for patients with cardiovascular (CVD) or other atherosclerotic disease, asymptomatic individuals at high risk of developing CVD, and their partners, enrolled to a preventive cardiovascular risk management programme in primary care is effective for smoking cessation in every day clinical practice.

Study design

EUROACTION PLUS is a randomised controlled intervention trial with clinical follow-up at 16 week.
Vascular patients and people at high risk of developing cardiovascular disease (CVD) who are current smokers, and their partners, will be identified from general practice medical notes and will be individually randomised to receive either a professional nurse coordinated smoking cessation service, which includes Varenicline, delivered in the context of the 16-week EUROACTION preventive cardiology programme, or to receive usual care with attention for all aspects of preventive cardiovascular risk management, however, without using Varenicline. The results of this smoking cessation service will be compared against usual care.

Intervention

In the Intervention arm, the cardiovascular screening and risk assessment will be performed at the
initial and 16-week interview for all patients and their partners. This will

include smoking status, diet,
physical activity, blood pressure, lipids, and diabetes management. Some psychosocial
measurements including assessment of anxiety and depression and quality of life will also be
undertaken. All participants will be offered comprehensive, family based, preventive cardiology
programme, including intensive smoking cessation intervention with Varenicline (for all patients and
partners who are smokers).

Study burden and risks

As the object of the trial is to reduce the risk of heart attacks and stroke, the participants can only benefit from their lyfestyle and onterh cardiovascular risk assessment. Varenicline is a licenced drug and any potential side effects will be monitored.
By excluding patients with psychiatric problems we will reduce the risk of such adverse effects as good as possible.
The burden related to this trial is the time-investment of the participating patients and the risk of a heamatoma by venapuncture.

Contacts

Public
Clinical Research Governance Office,Sir Alexander Fleming Building, Imperial College

Exhibition Road
London SW7 2AZ
GB
Scientific
Clinical Research Governance Office,Sir Alexander Fleming Building, Imperial College

Exhibition Road
London SW7 2AZ
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Vascular patients and partners;All patients with a medical diagnosis of coronary or other atherosclerotic disease (see below), and who have been smoking 5 or more cigarettes per day within the last month and are willing to make a quit attempt, 18 years of age or older, but less than 80 years, will be eligible for the comprehensive preventive cardiology programme, including smoking cessation service with Varenicline.;i) Acute myocardial infarction (STEMI or NSTEMI)
ii) Unstable angina
iii) Stable angina pectoris
iv) Elective revascularisation: coronary artery bypass graft (CABG), percutaneus coronary internvention (PCI)
v) Stroke
vi) Transient ischaemic attack (TIA)
vii) Peripheral vascular disease (PVD);The partners of all recruited coronary patients will also be identified and invited to participate in the preventive cardiology programme. Those who are smoking will also be offered the same smoking cessation service including Varenicline.;2. High*risk people and partners;All high risk people - smokers who have been smoking 5 or more cigarettes per day within the last month and willing to make a quit attempt, who meet the inclusion criteria (see below) will be eligible for the preventive cardiology programme, including smoking cessation service with Varenicline: ;Men and women, 50 years of age or older, but less than 80 years, who are smokers willing to make a quit attempt and either
i) are newly identified high multifactorial risk individuals: CVD risk equal or greater than 5% over 10 years (now or projected to age 60 years), according to the HeartScore risk estimation system; or
ii) have been treated with antihypertensive and/or lipid*lowering therapies; or
iii) have diabetes mellitus. ;The partners of all recruited high risk patients will also be identified and invited to participate
in the preventive cardiology programme. Those who are smoking will also be offered the same smoking cessation service including Varenicline.

Exclusion criteria

Patients with coronary artery disease or atherosclerotic vascular disease
* severe heart failure
* severe physical disability
* impaired cognitive function

* patients with acute coronary syndromes, with or without revasularisation, will not be included
in the study until 2 weeks has elapsed following their coronary event.
- hypersensitivity to Varenicline (active substance or to any of the inactive ingredients)
- history of suicidal attempt
- history of psychosis
- bipolar disorders
- panic disorders
- epilepsy
- history of alcohol dependence;High-risk people:;* history of coronary or other atherosclerotic disease
* severe heart failure
* severe physical disability
* impaired cognitive function
- hypersensitivity to Varenicline (active substance or to any of the inactive ingredients)
- history of suicidal attempt within the last 10 years
- history of psychosis
- bipolar disorders
- panic disorders
- epilepsy
- history of alcohol dependence

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2010
Enrollment:	212

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Chantix (USA)
Generic name:	varenicline
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	10-01-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-01-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-02-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
Other	71715857
EudraCT	EUCTR2009-012451-18-NL
CCMO	NL30487.041.10