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Antioxidants in the risk of cardiovascular disease

Submission date 23/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/11/2009	**Overall study status** Completed	
Last Edited 11/10/2011	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title

An observational cross-sectional cohort study of the protective role of antioxidants against oxidative stress and inflammation in patients with a risk of cardiovascular disease

Acronym
AOCARD

Study objectives
There is a link between plasma concentrations of beta-carotene and alpha-tocopherol, the level of systemic inflammation and oxidative stress in patients with advanced coronary artery disease. Our presumption is that beta-carotene and alpha-tocopherol both hold protective roles against oxidative stress and inflammation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital Ethical Committee on Human Research of Regional Hospital of Pardubice, Czech Republic approved on the 12th May 2006

Study design
Observational cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
Patients diagnosed with non-acute coronary angiography for chest pain will be entered into the study in one of two groups:
Group 1: significant stenosis of coronary arteries
Group 2: patients without any stenosis

Venous blood was obtained under standard conditions, from 7 to 8 am after fasting for at least 12 hours. For the determination of beta-carotene, alpha-tocopherol and malondialdehyde concentrations, blood was collected in tubes with ethylenediaminetetraacetic acid (EDTA)

covered with aluminium foil to avoid carotenoid oxidation and polymerisation by oxygen and light. Plasma was obtained by centrifugation of the blood samples at 1500 g for 20 minutes and immediately stored at -80°C in 1.5 ml amber polypropylene tubes.

A questionnaire was also provided for the evaluation of pharmacotherapy, intake of nutrition or vitamin supplements, smoking or other diseases such as hypertension or diabetes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Measured from standard venous blood collection (see interventions section):
1. Beta-carotene
2. Alpha-tocopherol
3. Malondialdehyde
4. Free radicals
5. High sensitivity c-reactive protein (hsCRP)
6. Interleukin-6 (IL-6)

Secondary outcome measures
Measured from standard venous blood collection (see interventions section):
1. High density lipoprotein (HDL)-cholesterol
2. Low density lipoprotein (LDL)-cholesterol
3. Triglycerides
4. Total cholesterol
5. Glucose
6. Fibrinogen
7. Ceruloplasmin
8. Albumin
9. Transferrin
10. Haemoglobin

Overall study start date
01/09/2008

Completion date
30/06/2009

Eligibility

Key inclusion criteria
Participants were recruited from the Department of Cardiology, Regional Hospital of Pardubice.

Group 1:
1.1. Both males and females, aged 45 - 69 years
1.2. Patients with non-acute chest pain
1.3. Significant stenosis (coronary angiography)

Group 2:
2.1. Both males and females, aged 45 - 69 years
2.2. Patients with non-acute chest pain
2.3. No stenosis (coronary angiography)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Renal, hepatic or oncologic disease
2. Intake of vitamin and nutrition supplements

Date of first enrolment
01/09/2008

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Czech Republic

Study participating centre
University of Pardubice
Pardubice
Czech Republic
532 10

Sponsor information

Organisation
Regional Hospital of Pardubice (Czech Republic)

Sponsor details

Kyjevska 44
Pardubice
Czech Republic
530 02

Sponsor type
Hospital/treatment centre

Website
http://www.nemocnice-pardubice.cz/

ROR
https://ror.org/01a5ke137

Funder(s)

Funder type
Government

Funder Name
Ministry of Education, Youth and Sports (Czech Republic) (ref: CR grant COST 926 OC 124; 0021627502)

Alternative Name(s)
The Ministry of Education, Youth and Sports, MŠMT, MŠMT, MEYS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Czech Republic

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/12/2010		Yes	No