

Antioxidants in the risk of cardiovascular disease

Submission date 23/10/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/11/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/10/2011	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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