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The effect of gamma-tocopherol supplementation on gamma-tocopherol status, antioxidant capacity and nitrosative stress in apparently healthy smokers

Submission date
09/01/2008

Registration date
21/02/2008

Last Edited
21/03/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
04-PG

Study information

Scientific Title
The effect of gamma-tocopherol supplementation on gamma-tocopherol status, antioxidant capacity and nitrosative stress in apparently healthy smokers

Study objectives
Additional dietary vitamin E will help alleviate risk of cardiovascular disease in apparently healthy smokers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Ulster Research Ethics Committee,13/05/2004, ref: 04/34

Study design
Double-blinded randomised placebo-controlled intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular risk

Interventions
Oral supplementation of 100 mg of gamma-tocopherol or a placebo. Supplementation is provided for 6 months. There is no further follow-up after the post-intervention samples are collected.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin E

Primary outcome measure
1. Tocopherol concentrations
2. Selenium concentrations
3. Inflammation markers

All primary outcome measures are assessed when samples are collected at baseline, month 3 and month 6.

Secondary outcome measures
1. Body composition measurements
2. Immune markers

All secondary outcome measures are assessed at baseline and month 6.

Overall study start date
31/03/2006

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Consenting adult men and women
2. Smoke five or more cigarettes per day
3. Between 18 and 50 years of age
4. In general good health

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Key exclusion criteria

1. Non-smokers
2. Pregnancy
3. Diagnosed chronic disease
4. Those who take vitamin E containing supplements or prescribed medication

Date of first enrolment
31/03/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Ireland

Northern Ireland

United Kingdom

Study participating centre
University of Ulster
Coleraine
United Kingdom
BT52 1SA

Sponsor information

Organisation
SafeFood, The Food Safety Promotion Board (Ireland)

Sponsor details
Cork Headquaters
7 Eastgate
Little Island
Cork
Ireland
-

Sponsor type
Government

Website
http://www.safefoodonline.com

Funder(s)

Funder type
Government

Funder Name
SafeFood, The Food Safety Promotion Board (Ireland) (ref: 04-PG)

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