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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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
1. Body composition measurements
2. Immune markers

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Northern Ireland

Ireland

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

Sponsor information

Organisation
SafeFood, The Food Safety Promotion Board (Ireland)

Funder(s)

Funder type
Government

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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes