

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

Submission date 09/01/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 21/02/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 21/03/2017	Condition category Circulatory System	☐ 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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Contact details

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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

Primary study design

Interventional

Study design

Double-blinded randomised placebo-controlled intervention study

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