

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

<b>Submission date</b> 09/01/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 21/03/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Julie Wallace

### Contact details

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Coleraine  
United Kingdom  
BT52 1SA

## 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