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# Role of antioxidant therapy in preventing diabetic kidney disease

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 13/11/2007 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 29/01/2009 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 26/10/2020 | Nutritional, Metabolic, Endocrine | |

**Plain English summary of protocol**

Background and study aims
The aim of this study is to investigate the role of antioxidants (vitamin E and/or selenium) in the prevention of kidney disease in patients with type 2 diabetes.

Who can participate?
Adult patients with type 2 diabetes

What does the study involve?
Participants are randomly allocated to take either vitamin E or placebo (dummy supplement) and to take either selenium or placebo. The method of intake is oral and the duration of intake is 3 years. Kidney function is assessed every 6 months.

What are the possible benefits and risks of participating?
All patients could potentially benefit from having their general health reviewed more frequently than is the case with their usual care. Those patients receiving active treatment may benefit from preservation of their kidney function in the longer term. There is a possibility that by having more regular interactions with the research team than usual new health problems might be uncovered. Should this happen there will be appropriate further investigation and/or treatment which may or may not affect the participant's ability to continue in the study.

Where is the study run from?
St George's University of London (UK)

When is the study starting and how long is it expected to run for?
March 2006 to July 2016

Who is funding the study?
St George's Hospital NHS Trust Charitable Trust Foundation (UK)

Who is the main contact?
Dr Kenneth Earle

# Contact information

### Type(s)
Scientific

### Contact name
Dr Kenneth Earle

### Contact details
St. George's Hospital NHS Trust
St. George's Hospital Medical School
Thomas Addison Diabetes Centre
Lanesborough Wing
London
United Kingdom
SW17 0QT

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
05/Q0803/57

# Study information

### Scientific Title
Role of antioxidant therapy in preventing diabetic kidney disease: a randomised, double-blind controlled study

### Study objectives
Susceptibility to kidney disease failure in patients with diabetes is associated with reduction in kidney blood flow due to a chemical imbalance called oxidative stress. Therefore, the supplementation of antioxidants may reverse it.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Wandsworth Local Research Ethics Committee, St George's Hospital, 01/08/2005, ref: 05/Q0803/57

### Study design
Randomised double-blind controlled 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 below to request a patient information sheet

## Health condition(s) or problem(s) studied
Type 2 diabetes

## Interventions
Two month washout period, then patients will be randomised to receive vitamin E 400 IU daily or placebo and 200 µg daily selenium or placebo. The method of intake is oral and the duration of the intake is 3 years.

## Intervention Type
Supplement

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Antioxidant supplementation

## Primary outcome measure
1. Change in renal blood flow
2. Change in serum creatinine and creatinine clearance
Assessments every 6 months

## Secondary outcome measures
1. Systolic blood pressure
2. Diastolic blood pressure
3. Total cholesterol
4. Total triglycerides
5. Beta-2 microglobulin
6. Haemoglobin A1c
7. F2-alpha isoprostanes
8. Monocyte vascular endothelial growth factor (VEGF) production
9. Total antioxidant capacity
10. Urine monocyte chemoattractant protein-1 (MCP-1)
11. Urine albumin:creatinine ratio
Assessments every 6 months

### Overall study start date
01/03/2006

### Completion date
27/07/2016

## Eligibility

### Key inclusion criteria
1. Adult ambulant patients with type two diabetes
2. Ability to give written informed consent

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
400

### Key exclusion criteria
1. History of cardiovascular disease
2. Evidence of severe renal impairment
3. Pregnancy
4. Malignancy

### Date of first enrolment
10/10/2011

### Date of final enrolment
29/04/2016

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre

**St George's University of London**
London
United Kingdom
SW17 0RE

# Sponsor information

**Organisation**
St George's University of London

**Sponsor details**
St George's Research Office
Cranmer Terrace
Tooting
London
England
United Kingdom
SW17 0RE

**Sponsor type**
University/education

**Website**
http://www.sgul.ac.uk/

**ROR**
https://ror.org/040f08y74

# Funder(s)

**Funder type**
Charity

**Funder Name**
St George's Hospital NHS Trust Charitable Trust Foundation (UK)

# 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 04/08/2016 | | Yes | No |
| Preprint results | results in preprint | 19/02/2019 | | No | No |