Role of antioxidant therapy in preventing diabetic kidney disease

| Submission date | Recruitment status No longer recruiting | [X] Prospectively registered | | |
|------------------------------|--|--------------------------------|--|--|
| 13/11/2007 | | [X] Protocol | | |
| Registration date 29/01/2009 | Overall study status Completed | Statistical analysis plan | | |
| | | [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 ORE

Sponsor information

Organisation

St George's University of London

Sponsor details

St George's Research Office Cranmer Terrace Tooting London England United Kingdom SW17 ORE

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 |