

Role of antioxidant therapy in preventing diabetic kidney disease

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

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
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United Kingdom
SW17 0QT

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double-blind controlled study

Study type(s)

Treatment

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(s)

1. Change in renal blood flow
 2. Change in serum creatinine and creatinine clearance
- Assessments every 6 months

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

St George's University of London

London

United Kingdom

SW17 0RE

Sponsor information**Organisation**

St George's University of London

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

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