# The effect of modest salt reduction on blood pressure and endothelial function in diabetic patients

Submission date	No longer recruiting	Prospectively registered	
23/04/2008		Protocol	
Registration date	Overall study status	Statistical analysis plan	
23/01/2009 Last Edited	Completed  Condition category	Results	
		Individual participant data	
19/07/2017	Circulatory System	<ul> <li>Record updated in last year</li> </ul>	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Rebecca Suckling

#### Contact details

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## Additional identifiers

Protocol serial number N0236194367

## Study information

#### Scientific Title

The effect of modest salt reduction on blood pressure and endothelial function in diabetic patients: a randomised cross-over study

## **Study objectives**

We propose that a moderate reduction in salt intake will improve blood pressure, endothelial function and damage to target organs without affecting insulin sensitivity.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Wandsworth Local Research Ethics Committee, 08/06/2006, ref: 06/Q0803/45

## Study design

Randomised cross-over study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Cardiovascular disease

#### **Interventions**

Individuals will have an initial two-week run-in period where dietary salt advice is given to achieve a salt reduction of 6 g. They are then randomised by computer-generated random allocation to either placebo or salt 6 g daily for six weeks in matched tablets. Both the study participants and the investigators are blinded. There is no washout period. At the end of the study, individuals are seen at 2 - 4 weeks for a follow up visit.

## Intervention Type

Other

## Primary outcome(s)

Casual systolic and diastolic blood pressure. Primary outcomes are measured at baseline and weeks 2, 5, 8, 11 and 14.

## Key secondary outcome(s))

- 1. Urinary albumin excretion
- 2. Ambulatory blood pressure monitoring (ABPM)
- 3. Endothelial function
- 4. Arterial stiffness

Secondary outcomes are measured at baseline and weeks 8 and 14.

## Completion date

01/10/2008

# Eligibility

## Key inclusion criteria

- 1. Age 30 to 80 years, either sex
- 2. Untreated blood pressure of greater than 120/70 mmHg with impaired glucose tolerance on oral glucose tolerance test or diet controlled type two diabetes

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

All

## Key exclusion criteria

- 1. Uncontrolled hypertension (blood pressure greater than 160/100 mmHg)
- 2. Type two diabetes on oral hypoglycaemic agents or insulin
- 3. Secondary hypertension
- 4. Uncontrolled heart failure or active ischaemic heart disease
- 5. Active malignancy or liver disease
- 6. Females who are pregnant, breast feeding or taking the oral contraceptive pill
- 7. Individuals started on lipid lowering therapy within the last three months

## Date of first enrolment

01/10/2006

#### Date of final enrolment

01/10/2008

## Locations

#### Countries of recruitment

United Kingdom

England

**SW17 0RE** 

Study participating centre
St George's University of London
London
United Kingdom

# Sponsor information

## Organisation

St George's University of London (UK)

#### **ROR**

https://ror.org/040f08y74

# Funder(s)

## Funder type

Charity

#### **Funder Name**

NHS R & D Support Funding (UK)

#### **Funder Name**

Hypertension Trust (UK)

Alternative Name(s)

## **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

Other non-profit organizations

#### Location

**United Kingdom** 

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type **Details** Participant information sheet

Date created Date added Peer reviewed? Patient-facing?

11/11/2025 11/11/2025 No