

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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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

Primary study design

Interventional

Study design

Randomised cross-over study

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

Study participating centre

St George's University of London

London

United Kingdom

SW17 0RE

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