ISRCTN41450337 https://doi.org/10.1186/ISRCTN41450337

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Rebecca Suckling

Contact details
Blood Pressure Unit
St George's University of London
Cranmer Terrace
Tooting
London
United Kingdom
SW17 0RE
-
rsuckling@sgul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Other

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

Secondary outcome measures
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.

Overall study start date
01/10/2006

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

Age group
Adult

Sex
Both

Target number of participants
50

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
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 (UK)

Sponsor details
Cranmer Terrace
Tooting
London
England
United Kingdom
SW17 0RE
-
sallen@sgul.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.sgul.ac.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

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