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Does sodium cause endothelial dysfunction in patients with chronic kidney disease (CKD)? A pilot study

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/04/2018	**Condition category** Surgery	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0112173573

Study information

Scientific Title
Does sodium cause endothelial dysfunction in patients with chronic kidney disease (CKD)? A pilot study

Study objectives
We propose to test the following hypothesis; that in subjects with mild-to-moderate CKD under conditions of high sodium intake, as compared to low-normal sodium intake:
1. The ratio [ADMA] Urine :[DMA] urine is increased
2. [ADMA] plasma in increased
3. Endothelium-dependent vasodilatation is reduced

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double-blind placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Urological and Genital Diseases: Chronic kidney disease (CKD)

Interventions
Double blind placebo controlled study of individuals with mild-to-moderate CKD. Subjects receive both Slow Sodium tablets (equivalent to 150 mmol/9 grams per day) and placebo tablets, with each administered for one week, in an order determined by random allocation. 'Study measurements' will be performed at baseline, and at the end of each week on study medications.
The specific experimental techniques are as follows:
1. Blood Pressure - Sitting and 24 hr ambulatory (taken with validated devices)
2. Routine biochemical investigations on blood and urine (the latter to include urinary sodium &

creatinine clearance)
3. Plasma & urine asymmetrical dimethylarginine (ADMA) - determined by commercially available ELISA.
4. Urinary dimethylamine (DMA) - determined by high pressure liquid chromatography
5. Forearm blood flow measurements - determined by venous occlusion plethysmography.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Essentially the 'outcome measure' is as detailed in the hypothesis above i.e. that on the high sodium part of the study (when receiving Slow Sodium tablets), participants will have increased levels of circulating (plasma) ADMA, increased urinary ADMA and reduced urinary DMA . It is also hoped that this will be paralleled by appropriate changes in endothelial function (ie that endothelium dependent forearm blood flow will occur in parallel with changes in ADMA).

Secondary outcome measures
Not provided at time of registration

Overall study start date
13/07/2005

Completion date
29/12/2006

Eligibility

Key inclusion criteria
1. Chronic kidney disease (as defined by calculated creatinine clearance of 30 to 89 ml/min/1.73m2 by Cockcroft-Gault formula)
2. 18-75 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Not Specified

Target number of participants
12

Key exclusion criteria
1. <18 or >75 years old
2. 3g/24hours of proteinuria
3. Calculated creatinine clearance<30 ml/min
4. Uncontrolled hypertension (defined as systolic BP >160 mmHg, diastolic BP>100 mmHg on/off anti hypertensive medication)
5. Diabetes mellitus
6. Tobacco smoking
7. Total fasting cholesterol .6 mmol/L
8. Uncontrolled heart failure OR active IHD (MI in last 3 months or current angina)
9. Chronic liver failure
10. Active malignancy

Date of first enrolment
13/07/2005

Date of final enrolment
29/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kent & Canterbury Hospital
Canterbury
United Kingdom
CT1 3NG

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Epsom and St Helier University Hospitals NHS Trust (UK), NHS R&D Support Funding

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