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

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

## Study type(s)
Treatment

## 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(s)

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).

### Key secondary outcome(s))
Not provided at time of registration

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
75 years

### Sex
Not Specified

### 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**
United Kingdom

England

**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

# Funder(s)

**Funder type**
Government

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

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration