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Comparison of the influence of low-dose supplementation with potassium citrate or potassium chloride on blood pressure, plasma and erythrocyte electrolyte concentrations and bone health biomarkers

Submission date 15/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/04/2006	**Overall study status** Completed	
Last Edited 06/08/2020	**Condition category** Circulatory System	

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
02/03-53

Study information

Scientific Title
Comparison of the influence of low-dose supplementation with potassium citrate or potassium chloride on blood pressure, plasma and erythrocyte electrolyte concentrations and bone health biomarkers

Study objectives
It is hypothesised that a sustained supplementation (6 weeks) with low-dose potassium (30 mmol per day), equivalent to the amount present in five portions of fruit and vegetables, would decrease blood pressure and would improve bone metabolism, by reducing bone resorption and increasing bone formation.
It is also hypothesized that a non-chloride potassium salt (potassium citrate) when compared to the chloride salts, might promote a further decrease in blood pressure, reduce bone resorption and increase bone formation. Finally it is hypothesised that the potassium-induced decrease in blood pressure might be related to changes in plasma and erythrocyte concentration of sodium and potassium.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval details not yet received as of 28/04/06

Study design
Randomised, double-blind, placebo-controlled trial with a parallel arm design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hypertension and osteoporosis

Interventions

Patients will be randomised to receive one of three treatments:
1. Placebo
2. Potassium citrate
3. Potassium chloride

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Potassium citrate and potassium chloride

Primary outcome measure
1. Mean change in systolic and diastolic blood pressure after 6 weeks of treatment
2. Mean change in biomarkers of bone resorption and bone formation
3. Mean change in erythrocyte and plasma electrolytes concentrations

Secondary outcome measures
Mean change in mean arterial pressure

Overall study start date
16/06/2004

Completion date
29/09/2005

Eligibility

Key inclusion criteria
To take part in the study, participants will be aged between 22 and 65 years and will have a body mass index (BMI) between 19 and 35 kg/m^2 and alcohol consumption of no more than 21 units (women) or 28 units (men) per week. Volunteers eligible for the study will have the average self-measured systolic blood pressure <160 and average self-measured diastolic blood pressure <105 mmHg (an average of 20 readings for both systolic and diastolic blood pressure). Those with blood pressure levels higher than these values will be advised to contact their general practitioners.
Subjects taking medications for which potassium supplementation is not contraindicated, or mineral and vitamin supplements, will be allowed to participate in the study with the provision that they will not discontinue to use these products.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120 healthy volunteers

Key exclusion criteria
The main exclusion criteria will be diseases or conditions that might involve collateral effects from potassium supplementation or interfere with its metabolism. These will be insulin dependent diabetes mellitus, non-insulin dependent diabetes mellitus, diabetes insipidus, cardiovascular diseases (including events of cardiac arrhythmia and peripheral arterial disease) or previous cardiovascular events, any kind of renal diseases, metabolic acidosis, current peptic ulcers, dysphagia, general digestive problems, gastric surgery, pregnancy and lactation. Women planning to become pregnant will also be excluded.
Other exclusion criteria will be the use of antihypertensive drugs, changes in lifestyle (e.g. dieting, start of new medication), the use of drugs known to interfere with potassium metabolism (cyclosporin, heparin, digoxin, anticholinergics) and prolonged use of non-steroidal anti-inflammatory drugs.

Date of first enrolment
16/06/2004

Date of final enrolment
29/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Deparment of Nutrition and Dietetics
London
United Kingdom
SW4 7RJ

Sponsor information

Organisation
King's College London (UK)

Sponsor details
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England
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SE1 9NN

Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
All costs related to the running of the trial and are covered by a modest grant (less than £20,000) from the Food and Drink Federation, which is supported by contributions made by affiliated member companies. The study is also partially supported by King's College Enterprises (cost of manufacturing the supplements).

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2008	06/08/2020	Yes	No