

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/08/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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/m² 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

Department 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