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The effect of replacing regular salt with SmartSalt® mineral salt on blood pressure in middle-aged subjects with high blood pressure or with mild hypertension

Submission date 11/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/01/2010	**Overall study status** Completed	
Last Edited 17/01/2012	**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
VESU 5070

Study information

Scientific Title
The effect of replacing regular salt with SmartSalt® mineral salt on blood pressure in middle-aged subjects with high blood pressure or with mild hypertension: a randomised controlled two-arm human study

Study objectives
The purpose of the study was to investigate the effect of replacing regular salt (NaCl) with SmartSalt® mineral salt on blood pressure in subjects with high blood pressure or with mild hypertension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Hospital District of Northern Savo approved on the 26th January 2009 (ref: DNRO 4/2009). An amendment of the protocol was approved on the 22nd September 2009.

Study design
Randomised double-blind (main study; follow-up was unblinded) controlled two-arm human study

Primary study design
Interventional

Secondary study design
Randomised controlled 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
High blood pressure/mild hypertension

Interventions
Test product: Smart Salt® mineral salt (sodium chloride [NaCl] 50%, potassium chloride 25%, magnesium ammoniumhexahydrate 25 %)
Placebo product: regular salt (sodium chloride, NaCl)

The study consisted of three periods: a screening period (duration: 4 weeks +/- 7 days), an intervention period (duration: 8 weeks +/- 7 days) and an optional follow-up period (duration: 28

weeks +/- 14 days). The screening period included two study visits (-4 weeks and -2 weeks) and the intervention period included four visits (0 weeks, +3 weeks, +6 weeks and +8 weeks) and the optional follow-up period included two visits (+12 weeks and +28 weeks). After the screening period, 25 subjects were randomised to use Smart Salt® as a table salt and Smart Salt® salted foods (main dishes, bread, sausages and cheese, representing over 50% of the sodium sources in the diet) and 25 subjects were randomised to consume an equivalent regular salt (NaCl) diet respectively for a 8-week period.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SmartSalt® mineral salt

Primary outcome measure
Change in systolic blood pressure during intervention period measured with automatic sphygmomanometer after 10 minutes resting in sitting position.

Secondary outcome measures
1. Change in diastolic blood pressure and mean of systolic and diastolic blood pressure and heart rate measured with an automatic sphygmomanometer after 10 minutes resting in sitting position. The measurement was repeated three times at intervals of at least two minutes and the mean of two last measurements was used as a result. The blood pressure measurements were made at visits -4 weeks, -2 weeks, 0 weeks, +3 weeks, +6 weeks, +8 weeks and at optional follow-up visits +12 weeks and +28 weeks.
2. 24-hour urinary sodium, potassium, magnesium and creatinine excretion measured just before the intervention (-1 day) and at visit +8 weeks
3. Urine pH measured at the study visits 0 weeks, +3 weeks and +8 weeks by stick test
4. Concentrations of plasma sodium, potassium, magnesium and creatitine measured at visits -4 weeks, 0 weeks and +8 weeks
5. The dietary intake of sodium calculated from 24-hour urinary sodium excretion and study subject's diaries
6. Body weight measured with calibrated digital scales at visits -4 weeks, 0 weeks, +3 weeks, +6 weeks and +8 weeks and optional follow-up visits +12 weeks and +28 weeks
7. Optionally concentrations of plasma renin, plasma aldosterone taken at visits 0 weeks and +8 weeks and serum C-peptide taken at visits 0 weeks, +3 weeks and +6 weeks and +8 weeks

Overall study start date
09/02/2009

Completion date
04/11/2009

Eligibility

Key inclusion criteria

1. Male or female aged 25 to 75 years (home-living subject)
2. High blood pressure or mild hypertension (systolic blood pressure [SBP] 130 - 159 mmHg or diastolic blood pressure [DBP] 85 - 99 mmHg) (mean of two measurements during the run-in period (visits -4 week and -2 week)
3. Body mass index 23 - 40 kg/m^2
4. Stable body weight (self-reported weight gain or loss less than 3 kg in the past three months)
5. Voluntarily signed informed consent (including willingness to fast 10 - 12 hours before blood samples and abstain from alcohol 2 days prior to blood sampling and abstain from cigarettes, caffeine and physical exercise at least 30 minutes before measurements)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Antihypertensive drug treatment
2. Regular non-steroidal anti-inflammatory drug (NSAID) treatment and the use of ciclosporin or tacrolimus
3. Cardiovascular disease (myocardial infarction, unstable angina pectoris, coronary artery bypass graft, percutaneous transluminal coronary angioplasty, temporal ischaemic attack within six months prior to screening) including stroke and congestive heart failure
4. Anaemia, abnormal electrolytes, proteinuria, abnormal liver, kidney and thyroid function, except subjects on thyroid replacement therapy upon decision of investigator
5. Secondary hypertension
6. Diabetes (type 1 and type 2 diabetes)
7. History of cancer or malignant disease within the past five years
8. Low-salt diet: six or less points in the salt intake test (Finnish Heart Association, Helsinki)
9. Previous remarkable use of mineral salts products in daily diet (greater than 30% substitution)
10. Dietary restriction (coeliac disease, serious lactose intolerance, low-carbohydrate diet, sodium restriction, allergy to ingredients of test foods)
11. Alcohol abuse: subjects consuming more than 14 portions of alcohol per week
12. Drug abuse
13. Pregnant and lactating mothers
14. Women planning for pregnancy during the study
15. Participation in clinical trials 30 days prior to this study
16. Participation to other clinical trials during this study

Date of first enrolment
09/02/2009

Date of final enrolment
04/11/2009

Locations

Countries of recruitment
Finland

Study participating centre
Neulaniementie 2 L 6
Kuopio
Finland
70210

Sponsor information

Organisation
Smart Salt Inc. (USA)

Sponsor details
c/o Tapio Mäki
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Sponsor type
Industry

Website
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ROR
https://ror.org/01vvp4329

Funder(s)

Funder type
Industry

Funder Name
Smart Salt Inc. (USA)

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	02/09/2011		Yes	No