ISRCTN50989296 https://doi.org/10.1186/ISRCTN50989296

Understanding the role of potassium on hydration and fluid balance

Submission date
28/06/2016

Recruitment status
No longer recruiting

Registration date
29/06/2016

Overall study status
Completed

Last Edited
17/12/2019

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The amount of different electrolytes (uncharged molecules such as potassium and sodium) of fluids drunk has a large impact on the amount of fluid retained by the body or excreted as urine (net fluid balance). There is a lot of evidence regarding improved net fluid balance responses with consumption of fluids particularly high in sodium, but there is now a greater focus on the role of high potassium (K+) drinks in triggering a positive fluid balance response. There have been a number of studies that have attempted to highlight the effectiveness of potassium consumption but the results have been open to interpretation, possibly due to the role of other drink components and the variability in the method of dehydration and/or rehydration. A previous study highlighted the potentially different hydration potential of certain commercial drinks with equal carbohydrate content yet different potassium content. Recently, there has been a lot of promotion for coconut water being effective for hydration due to their potassium content helping to maintain a positive fluid balance. However, studies conducted to date have shown no additional benefit to hydration status with coconut water consumption or high potassium containing drinks, and no study has systematically investigated the effects of consuming a range of potassium doses reflecting the composition of a range of commercial coconut water products. The aim of the study is to find out the best potassium content of ingested fluids for maintaining net fluid balance following consumption of fluids of increasing potassium content.

Who can participate?
Healthy, male University of Stirling students, aged 18-35

What does the study involve?
Participants are required to make four separate visits to the study centre. Before each study visit, participants are asked not to eat or drink anything for 12 hours and to avoid caffeine, alcohol or strenuous exercise for 24 hours. In addition, the night before each study visit, participants are asked to come to the laboratory to drink 500ml of bottled water over a two hour period before having their body mass when hydrated is measured using electric scales and through providing a urine sample. Participants are randomly allocated to drink one of four test drinks on each study visit. Upon arrival, body mass when dehydrated is then measured using electric scales before the participant drinks one litre (4 x 250ml) in 60 minutes of the test drink.

The test drinks contain different concentrations of potassium, either 0mmol, 30mmol, 45mmol or 60mmol. Once the test drink has been consumed, participants are asked to provide urine samples at hourly intervals during a two hour observation period. Following the two hour observation period,a final body mass measurement is taken.

What are the possible benefits and risks of participating?
Participants benefit from receiving information about how their body processes the fluids they drink. As participants are required to drink one litre of potassium-containing fluid at a time, there is a risk of digestive discomfort or the urge to urinate more.

Where is the study run from?
Health and Exercise Sciences Research Group, The University of Stirling (UK)

When is study starting and how long is it expected to run for?
October 2015 to March 2016

Who is funding the study?
University of Stirling (UK)

Who is the main contact?
Dr Stuart Galloway
s.d.r.galloway@stir.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Stuart Galloway

ORCID ID
http://orcid.org/0000-0002-1622-3044

Contact details
Health and Exercise Sciences Research Group
University of Stirling
Stirling
United Kingdom
FK9 4LA
+44 1786 473171
s.d.r.galloway@stir.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized trial assessing the impact of graded potassium content of beverages on restoration of fluid balance in adult males

Study objectives
A dose-response effect would be in evidence, whereby consumption of increased doses of potassium would result in an increased net potassium balance, eliciting an increased net Fluid Balance response.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Stirling Health and Exercise Science Research Group Ethics Committee, 22/12/2015, ref: #775

Study design
Randomized cross-over design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

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
Hydration status

Interventions
Participants attend the laboratory for four experimental trial days which are conducted in a single blind randomised cross-over fashion at the same time of day and exactly one week apart.

On each of the trial days, participants arrive at the laboratory in the morning following a 12 hour period of food and fluid restriction to induce a mild hypohydration (~1-2% body mass loss). On arrival at the laboratory participants empty their bladder and bowels and a baseline urine

sample is collected. This is followed by assessment of baseline near nude body mass. After collection of baseline samples, participants consume a fixed volume (1L) of an assigned drink over a 1 hour period (4 x 250ml boluses provided in 15 minute intervals). Participants consume one of four fresh laboratory-prepared drinks per trial with different potassium content: 0mM [K+] (0K; control), 30mM [K+] (30K), 45mM [K+] (45K) and 60mM [K+] (60K) respectively. The composition of the drinks ingested is based on a standardized 3% carbohydrate (dextrose) solution containing 5mM sodium (Na+). Participant's fluid balance (urine output and near nude body mass) is monitored immediately post drinking and at hourly intervals during a subsequent 2 hour follow-up observation period. Participants remain seated in the laboratory throughout the whole trial period. On completion of the follow-up period a final urine sample and near nude body mass assessment is taken before participants leave the laboratory.

Intervention Type
Other

Primary outcome measure
1. Net Fluid Balance assessed at hourly intervals during the 2 hour observation period (fluid consumed minus cumulative urine output) in each study visit
2. Hydration Index assessed using total urine output on control divided by total urine output at the culmination of the 2 hour observation period in each study visit

Secondary outcome measures
1. Sodium and Potassium net balances (intake minus urine losses) is assessed immediately post-consumption and at hourly intervals following drink consumption for 2 hours on each trial day using the flame photometry method within 5 days of urine sample collection
2. Body Mass measurements are taken using electronic scales for comparison between participants' 'hypohydrated' body mass (pre-drink consumption) and body mass at the culmination of the 2 hour observation period (2 hours post-drink consumption) on each trial day
3. Urine osmolality is assessed using the freezing point depression method within 48 hours of urine sample collection at baseline (pre-drink consumption) and at hourly intervals following drink consumption for 2 hours on each trial day

Overall study start date
05/10/2015

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Healthy male volunteers
2. Aged 18-35
3. No known cardiovascular, renal or metabolic disease/disorder
4. Moderate activity level

Participant type(s)
Healthy volunteer

Age group

Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Male

Target number of participants
12 (n=12 observations for all trials)

Total final enrolment
20

Key exclusion criteria
1. Female participants
2. Participants currently taking diuretic and/or blood pressure medication
3. Previously/currently suffering from cardiovascular, renal or metabolic disease/disorder
4. Participants actively seeking to gain/lose weight

Date of first enrolment
11/01/2016

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Stirling
Health and Exercise Sciences Research Group
Stirling
United Kingdom
FK9 4LA

Sponsor information

Organisation
University of Stirling

Sponsor details
Health and Exercise Sciences Research Group
Stirling
Scotland
United Kingdom
FK9 4LA
+44 1786 473171
s.d.r.galloway@stir.ac.uk

Sponsor type
University/education

Website
www.stir.ac.uk

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
University/education

Funder Name
University of Stirling

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a relevant nutritional journal.
2017 results presented at International Sports and Exercise Nutrition Conference 2017

Intention to publish date
31/07/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request