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Does bicarbonate of soda affect water balance when it is prescribed to treat people with kidney failure?

Submission date
04/09/2007

Recruitment status
No longer recruiting

Registration date
23/01/2008

Overall study status
Completed

Last Edited
01/03/2019

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The kidneys are important in controlling the levels of many different chemical levels in the blood. They also control the amount of salt (sodium) and water in the body, which in turn can affect blood pressure. If the kidneys are not working properly, a condition called chronic kidney disease, blood pressure can be high. This is called hypertension. Hypertension can cause further damage to the kidneys and also damage the heart and blood vessels. Controlling high blood pressure is a very important part of looking after chronic kidney disease.
Acid levels can also build up in the blood in chronic kidney disease. Doctors often prescribe tablets called sodium bicarbonate (which is bicarbonate of soda, or baking powder in tablet form) to correct acid levels. Because these tablets contain sodium, there is a possibility that they could have an effect on sodium and water retention or blood pressure in people with kidney disease. The aim of this study is to try and measure the effects of sodium bicarbonate on body water in people with chronic kidney disease.

Who can participate?
Adults with chronic kidney disease

What does the study involve?
The study involves having measurements of blood pressure and body water at two time points, 4weeks apart. In the 4-week interval between the measurements, participants will take three extra tablets three times a day. Body water is measured in two ways. One method involves a simple electric test called bioimpedance. Bioimpedance uses a small electric current that is passed between two electrodes placed on the back of one hand and two electrodes placed on the top of one foot, while lying comfortably on a couch. The electric current is very low, cannot be felt and is completely safe. The other method involves drinking two small beakers of colourless liquid. One tastes just like water. The other is slightly salty. Both are harmless. A sample of blood and saliva are taken just before the drinks. A further blood sample is taken 4 hours after the drinks and further saliva samples at 4, 5 and 6 hours after the drinks. Participants also agree to provide a record of their blood pressure medication and to provide a 24-hour urine collection at the beginning and end of the study.

What are the possible benefits and risks of participating?
There are no immediate health benefits to taking part. Participants are helping us to understand their medical condition more fully and this might lead to better or safer treatment in the future. It is possible that participants could retain fluid or have an increase in blood pressure. The study is short and any changes will be picked up by the study team. Any changes should be temporary and go away at the end of the study.

Where is the study run from?
York Hospital

When is the study starting and how long is it expected to run for?
June 2007 to November 2011

Who is funding the study?
British Renal Society (UK)

Who is the main contact?
Dr Colin Jones, colin.h.jones@york.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Colin Jones

Contact details
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE
-
colin.h.jones@york.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SOB06/version3.0

Study information

Scientific Title

The effects of oral sodium bicarbonate on extracellular water in patients with chronic renal failure

Study objectives
Does oral sodium bicarbonate have an effect on extracellular water or blood pressure in patients with chronic kidney disease?

On 14/02/2012 an update was received stating that the trial end date was extended following a trial halt period. Trial was terminated early on 21/11/2011 at 40 subjects due to inability to recruit sufficient patients within a reasonable timescale. Relevant authorities have been notified. Sample analysis is currently taking place. Statistical analysis and publication of results will follow later this year.

On 15/02/2012 the overall trial end date was changed from 30/09/2008 to 21/11/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Riding Local Research Ethics Committee, 21/08/2006, ref: 06/Q1104/108

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Chronic kidney disease

Interventions
Oral sodium bicarbonate 1.5 g three times a day for 4 weeks versus placebo. Follow up is complete at the end of the 4-week treatment period.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Sodium bicarbonate

Primary outcome measure
Extracellular water and total body water measured by bromide space and deuterium dilution at 4 weeks.

Secondary outcome measures
The following will be assessed at 4 weeks:
1. Blood pressure
2. Bio-impedance measures of total body water (TBW) and extracellular fluid (ECF)

Overall study start date
06/06/2007

Completion date
21/11/2011

Eligibility

Key inclusion criteria
1. Chronic kidney disease (CKD) (creatinine greater than 180 mcmol/l or glomerular filtration rate [GFR] less than 60 ml/min)
2. Aged over 18 years, male and female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Need for dialysis
2. Already taking oral sodium bicarbonate
3. Uncontrolled hypertension
4. Peripheral oedema
5. Nephrotic syndrome
6. Congestive cardiac failure

Date of first enrolment
06/06/2007

Date of final enrolment
21/11/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
York Hospital
Wigginton Rd
York
United Kingdom
YO31 8HE

Study participating centre
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
York Hospitals NHS Trust (UK)

Sponsor details
York Hospital
Wigginton Road
York
England
United Kingdom
YO31 8HE
-
caroline.mozley@york.nhs.uk

Sponsor type

Hospital/treatment centre

Website
http://www.yorkhealthservices.org/

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Charity

Funder Name
British Renal Society (UK) (ref: 05-008)

Alternative Name(s)
BRS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because this was not part of the consent process.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/01/2019	01/03/2019	Yes	No