LOCAL SITE Headed paper
www.bicarb.org.uk

PARTICIPANT INFORMATION SHEET

BICARB Study

The BiCARB Study

Does oral sodium bicarbonate therapy improve function and quality of life in older patients with chronic kidney disease and low-grade acidosis?
A multicentre randomized placebo controlled trial

We would like to invite you to participate in a research project which is a collaboration between [local PI] and Dr Miles Witham at the University of Dundee, Scotland. We believe it to be of potential importance. However, before you decide whether or not to participate, we need to be sure that you understand firstly why we are doing the study, and secondly what it would involve if you agreed to take part. We are therefore providing you with the following information. Please take time to read it carefully and be sure to ask any questions you have, and, if you want, discuss it with others. We will do our best to explain and provide any further information you may ask for now or later. You do not have to make an immediate decision.

Why are we doing this study?

Many people with reduced kidney function have higher than usual levels of acid in the blood. Higher levels of acid may worsen kidney function, blood vessel health and bone health, as well as stopping your muscles from working as well as they should. This in turn may make people feel tired and reduce quality of life. When these symptoms occur it is called chronic kidney disease.

Acid levels can be treated with sodium bicarbonate (used in baking powder); this is used as a treatment in some people with reduced kidney function and high levels of acid. We do not know whether the benefits of this treatment (on muscle, bone, kidneys, blood vessels and quality of life) are greater that the potential side effects (such as raising blood pressure, fluid retention and having to take extra tablets.)

Why have I been contacted?
You have been contacted because you are over the age of 60 years and have reduced kidney function.

Do I have to take part?
It is up to you to decide. Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason and without this affecting your future medical care or your relationship with medical or nursing staff looking after you. If you, Dr [PI] or one of your clinicians decides you should withdraw from the study, we would like your permission to retain and analyze the data already collected.

What will happen to me if I take part?
The study takes 2 years in total to complete.

The study is of randomized, doubled blind design. This means that you will be asked to take medication by mouth three times a day. This will either contain bicarbonate, or a placebo (dummy) medication. The one that you will be given is decided in a random way (a bit like tossing a coin, but done by a computer.) Neither you nor the research team will know which you are taking until after the study is finished. This means that the results of the study cannot be influenced by you or the researchers knowing what you are taking.

You will be asked to come to [LOCAL HOSPITAL, SITE DEPENDENT] on six or seven occasions over the two year study. We can reimburse travelling expenses or provide a taxi to transport you to [NAME OF HOSPITAL] and back for each visit. We will try and make sure that these visits happen when you are at [NAME OF HOSPITAL] for other clinic appointments.

The first visit is a screening visit to make sure that the study is suitable for you. It will last for approximately 30 minutes. We will ask you to sign a consent form indicating you wish to take part in the study. We will measure your blood pressure 3 times while you are sitting down. We will then take a teaspoon of blood, and ask about your medicines and illnesses and check your hospital notes. If the study is suitable for you, we will then ask you to come along for the baseline study visit (depending on how recent you have had blood samples taken at clinic or by your GP, we may be able to combine your screening visit and the next visit.). At this visit (approximately 90 minutes):

- We will measure your blood pressure and pulse 3 times while you are sitting down. We will check your height and weight

- We will take a blood test (about four tablespoons.) Some of the blood taken will be tested straight away in the local NHS laboratory, while some will be transferred to, stored and analysed at the end of the study at specialist laboratories by members of the study team (research bloods.) With your consent, tiny samples of blood serum and plasma obtained from these research bloods will be stored for up to 15 years in a clinical laboratory at the University of Dundee under the custodianship of Dr Miles Witham (Chief Investigator.) Your research bloods are stored using a unique study code which is non-identifiable. Blood samples are not taken for genetic testing.

- We will ask you to bring a urine sample with you

- We will give you a health diary to complete which will record any health problems you may have had in the previous month

- You will be asked to do some mobility tests: - standing tests, balance tests, timed getting up from a chair and a test to measure your hand grip strength

- You will be asked to walk up and down a corridor for six minutes at your own pace. We will measure how far you can walk in that time

- We will ask you two questionnaires about your quality of life and how your kidney problems affect your quality of life

- We will issue your study tablets

- We will issue you with a study pack which will contain: contact and appointment cards and a diary to record if you have experienced any falls.

We will ask you to return for further visits after three months, six months, a year, and at two years, where we will repeat the above tests. Each visit will take around an hour to complete. For each visit we ask you to bring all your study medication containers (empty or full) and your diary.

At the 3 month visit we take a blood sample to measure your sodium bicarbonate level. If it is found to be below a certain level we will ask you to increase your study medication to two tablets three times a day.

However, we will not receive this result straight away, so we will send you home from the visit with enough medication to last a further seven days. As soon as we receive your results we will send your new batch of tablets to your home by registered post or to your GP practice for you to collect with instructions of the dose you should take which will either be to stay the same, or to increase the number of tablets. We will give you a call as soon as we know that you have received your tablets to go over the dose requirements and answer any questions you may have.

You will continue on this dose for the rest of the study. If you are having any difficulties or experiencing any side-effects taking the tablets, please call, so we can discuss possible solutions.

We will give you a call at 15 and 21 months after you have started the study. These brief telephone calls will check that you are keeping well and managing to take the study medication. In between these two calls, at 18 months, we will ask you to come to hospital for a brief visit to collect your next supply of study medication and ask a few questions about your general health.

In addition, we will send you a copy of the study's Newsletter which will keep you up-to-date on the study's progress and if you have access to the internet you can log onto the study's website; www.bicarb.org.uk for updates.

What is being tested?
Sodium bicarbonate is used in baking powder. It has the ability to neutralise (mop up) the high levels of acid that can occur in the blood when the kidneys do not get rid of acid as well as they should.

Will taking part in the study affect your usual care?
We will not alter any of your other medication or interfere with your other treatment in any way. You will continue to be seen by your GP and by any hospital clinics that you usually attend.

What are the possible discomforts, risks and side effects?
This dose of sodium bicarbonate is commonly used in people with reduced kidney function. Elevated blood pressure, fluid retention and bloating are experienced by some people, and we will be asking you about these side effects at each visit. Having blood taken can cause some bruising. The blood pressure cuff causes mild discomfort to some people.

What are the benefits of taking part in the study?

You will be monitored closely during the study by the study team. The tests will give us information about the function of your kidneys and general well being. If any of these investigations reveal any new abnormality we will either discuss this with your GP (with your consent) or refer you to a specialist clinic [HOSPITAL] (whichever seems most appropriate.) The study may not immediately benefit you, but if the results of the study are positive this may change the practice of managing patients with reduced kidney function just like you.

What are my rights?

If you have a complaint about your participation in the study you should first talk to a researcher involved in your care. You can ask to speak to a senior member of the research team or the Complaints Officer for NHS [RELEVANT BOARD/TRUST].

Complaints and Claims Manager
[LOCAL CONTACT DETAILS]

In the event that something goes wrong and you are harmed during the study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Dundee or NHS [RELEVANT TRUST] but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate.)

Will my GP know about this research project?

With your permission we will inform your GP of your participation, any clinical results, and of any new medical problem we find as a result of your participation in the study.

Will my taking part in this study be kept confidential?

All the information that is collected about you during the course of this study will be kept strictly confidential. There will be two sets of information obtained during the study. One set will be routine blood tests analysed by local NHS laboratories and the other, the research data obtained from research blood samples and study procedures. The routine blood test results obtained will be stored indefinitely using your name and unique hospital record number within the NHS clinical system and can be made available to specialist doctors for your future health care needs.
Your research data will be stored using a unique study code which is non-identifiable. All written information will be kept in a locked filing cabinet in a

locked room. Any web-based data will be stored in a secure password protected central database at Health Informatics Centre, University of Dundee. Only individuals directly involved with the study will have access to this information. It is a requirement of the regulators that your records in this study, together with any other relevant medical records, be made available for scrutiny by appropriate monitors from Tayside Medical Science Centre (TASC) and the Regulatory Authorities. This procedure is routine and carried out by fully qualified officials, and data confidentiality is preserved at all times.

At the end of the study the confidential records will be kept for 15 years and then destroyed. The confidential handling, processing, storage and disposal of data are in accordance with the Data Protection Act1998.

Will I continue to receive the medication used in this study after it finishes?

Not routinely. The study is designed to give an indication of possible benefit from the medicine being tested and it may be some time before we can be sure about how useful it actually is. However, your Renal Physician or GP may make the decision whether or not to prescribe bicarbonate therapy after your study participation ends.

What will happen to the results?

The results will be examined by the researchers who have organised the study and a short report will be produced. You will not be identified in this report. The results will be shared with the funder for the study (The National Institute for Health Research.) The results will then be published in scientific journals. Again, you will not be identified in any journal articles. If you would like the results of the study please inform the research team.

Who is organizing and funding this research?

The study has been organised by Dr Miles Witham and colleagues at the Universities of Dundee, Aberdeen and King's College London, along with colleagues in Canterbury. The study is funded by the National Institute for Health Research.

Who has reviewed the study?

The East of Scotland Research Ethics Service REC 2 which has responsibility for scrutinising proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics.

For further information contact:
Research Nurse **for each centre** on telephone [local number] and [e-mail address].
PI for each centre on telephone [local number] and [e-mail address].

If during the study you become unwell or are concerned, as well as the usual services provided by the NHS such as [SCOTLAND NHS24 tel: 111 /or ENGLAND NHS111 tel: 111], you can also contact the study team during normal working hours on [Contact Number]. If you are unwell and need urgent advice or assistance do not delay in seeking further advice or treatment as usual through the NHS services.

Thank you for reading this information sheet and considering taking part in this study. If you would like more information or want to ask questions about the study please contact the study team on the number/addresses above.

NHS
National Institute for Health Research

BiCARB STUDY - VISIT SCHEDULE

ASSESSMENT/PROCEDURES	STUDY VISITS (months) – approximately 1½ hours						
	Screening*	Baseline*	3	6	12	18	24
Informed Consent	X						
Medical History / Demographics	X						
Safety Assessments			X	X	X	X	X
Blood Sample	X	X	X	X	X		X
Urine Sample		X	X	X	X		X
Questionnaires		X	X	X	X		X
Blood Pressure	X	X	X	X	X		X
Mobility Tests		X	X	X	X		X
Height		X					
Weight, Leg/Arm Muscle Measurements		X	X	X	X		X
Hand Grip Strength		X	X	X	X		X
Six Minute Walk Test		X	X	X	X		X
Study Medication (dispensed/collected)		X	X (posted)	X	X	X	Collected only
Study Nurse Phone Call			X		at 15 and 21 months		
Screening and Baseline Visits may occur at the same time, depending upon recent blood test results.							