Institutional Review Board
APPROVED
1/3/2013 through 11/28/2013
Protocol #: 2012-684

ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY
MONTEFIORE MEDICAL CENTER

Individual Information and Consent Form

You are being asked to join this research study.
The title of the study is: Intra-dialytic acid-base changes and organic anion production with standard versus low bicarbonate hemodialysis

The study is being done under the supervision of:

Principal Investigator (Research Study Doctor): Matthew Abramowitz, MD, MS
Office Address: Ullmann 615, 1300 Morris Park Ave, Bronx NY 10461
Telephone #: 718-430-8566
Protocol #: 2012-684-000

DO I HAVE TO TAKE PART IN THIS RESEARCH STUDY?

- Your participation is voluntary. This means that you decide whether or not you want to join the study after speaking with the researcher, or other member of the research team.
- If you decide to take part in this study you will be asked to sign this consent form. Your signature means that you agree to be a subject in this research.
- After reading this form and having a discussion about what it says, you should ask all the questions you want to ask. You should take as much time as you need to make a decision.
- If you do not understand some of the terms used in this form, ask the person who is discussing the study with you to give any additional information that may make this easier to understand.
- You do not have to consent to participate in the study immediately, or ever. Take time to decide whether or not you wish to join. You may take home a copy of this consent form to think about it or discuss the information with family or friends before you decide.
- If you decide not to participate the care providers at this facility will give you all of the standard care that is appropriate for you.
- You will be given a copy of this form whether or not you agree to participate in this study. Do not sign the form unless you have had all your questions answered and understand exactly what is involved.
- If you decide to take part you are still free to withdraw at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility.

STUDY SPECIFICS

WHY HAVE I BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You have been asked to participate in a clinical trial because you have kidney disease which currently requires hemodialysis.

If you decide to take part in this study, you will have 2 dialysis sessions as part of the study, one with standard dialysate and one with low-bicarbonate dialysate.

If you decide to take part in this study, you will be asked questions to be sure that you qualify for the study.

WHY IS THIS RESEARCH STUDY BEING DONE?

- The normal kidneys remove acid. When people have kidney disease, acid can build up in the body. Hemodialysis corrects this acid build up. We are testing to examine the changes in acid-base status which occur during dialysis and the ability to maintain a relatively stable acid-base equilibrum using high-bicarbonate versus low-bicarbonate dialysate.
- We will also examine the organic acid production during hemodialysis, its importance as a determinant of acid-base status, and the effect of high-bicarbonate versus low-bicarbonate dialysate on organic acid production.
- These studies will help to decide the right amount of bicarbonate in the dialysate to use for studies that we plan to do in the future.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

- You will come to the Jack D. Weiler Hospital dialysis unit for 2 dialysis sessions on your regular dialysis days, about one week apart.
- At the first session, you will recieve standard chronic dialysis with high bicarbonate dialysate (37 mEq/L + 4 mEq/L acetic acid); very similar to the treatment you receive as part of usual care. At the second session, you will receive hemodialysis with low bicarbonate dialysate (27 mEq/L + 4 mEq/L acetic acid).
- *All blood samples will be drawn from the lines connecting you to the dialysis machine as per usual practice in the dialysis units. No phlebotomy will be required to obtain these samples.*
- At the first session, you will be asked questions about your medical history and medications. We will collect other information about your dialysis from your dialysis chart.
- At each dialysis session you will be asked to walk a fixed distance while reciting the alphabet. You will also be asked to solve a puzzle.
- At each dialysis session, we will collect blood and dialysate samples approximately every 30-45 minutes for acid-base status and measurement of organic acids. No more than 80 milliliters (between 5 and 6 tablespoons) of blood will be drawn at each session.
- Blood samples will also be taken 30 minutes and 1 hour after the completion of the hemodialysis session in order to provide more useful information about changes that occur immediately after dialysis. This sample will be no more than 5 millilters (one teaspoon) of blood.
- **WHAT ARE THE POSSIBLE SIDE EFFECTS, DISCOMFORTS, RISKS OR INCONVENIENCES I CAN EXPECT FROM BEING IN THIS RESEARCH STUDY?**

Previous studies of changing the bicarbonate in the dialysis prescription have not noted any side effects

resulting from this change. However, here is a list of the risks associated with this research:

- Rarely changes in blood pressure may occur.
- Stomach upset and changes in appetite could also occur.
- In addition, a temporary, harmless "black and blue" may develop.
- Very rarely, fainting may occur.

ARE THERE LIKELY TO BE ANY BENEFITS TO TAKING PART IN THIS RESEARCH STUDY?

You will not benefit at this time from being in this research study. However the information learned from this study may, in the future, benefit you and other people receiving dialysis by improving our knowledge of how best to prescribe your treatment.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS RESEARCH STUDY?

- You may choose not to participate in this study and continue your standard hemodialysis care from your provider

WILL I BE PAID FOR BEING IN THE STUDY?

- You will be paid $50 dollars for participating in this study after completion of the protocol.

WHO MAY SEE MY RECORDS?

- The research records will be kept private and your name will not be used in any written or verbal reports.
- Your research records and medical records may be inspected by members of the research team that participate in this study.
- The researcher and research staff will review your medical records and will keep the information private.
- The research records will be kept in a secured manner and computer records will be password protected.
- The people who reviewed this research study as members of the Einstein Institutional Review Board (IRB) may also review your research and medical records.
- The Office of Human Research Protections (OHRP) may also review your research study records.
- All of these groups have been requested to keep your name private.

WILL THERE BE ANY COSTS TO ME?

- There will be no costs to you for participating in this study.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

Researcher's Name: Matthew Abrmowitz, MD, MS
Office Address: Ullmann 615, 1300 Morris Park Ave, Bronx, NY 10461
Office Phone: 718-430-8566

- If any questions arise related to this research project, or you believe you have any injury related to

this study, you can call the researcher above.
- You may also call the study coordinator Williams Paredes, BS 718-430-3088
- If you have questions regarding your rights as a research subject, you may also call the Manager of Einstein IRB at (718) 430-2253, Monday through Friday between 9 AM and 5 PM.

WILL ANY OF THE SAMPLES (BLOOD, TISSUE, DNA) TAKEN FROM ME BE USED FOR FUTURE RESEARCH STUDIES?

USE OF IDENTIFIED SPECIMENS FOR FUTURE RESEARCH:

In addition to the research you are consenting to under this research study, Dr. Matthew Abramowitz or other researchers at this or other institutions may wish to study the samples in future research, including genetic analysis. These samples, taken from your body, would be able to be linked back to you. Information about you may be shared with other researchers who will keep the information confidential. However, it is possible that information about you may become known to people other than the researchers.

At this time, the researcher does not know what the future studies will be. Your specimens may also be submitted to a tissue/cell/DNA bank. The specimens may be kept for a long time and may exceed 50 years. You have the right to withdraw consent to use of the tissue for future use at any time by contacting the supervisor of the study named on the first page of the consent. Unused specimens will be destroyed.

In some research using human blood or tissue, the specimens and their parts may enable researchers to develop medical tests or treatments that have commercial value. You will not receive any money that may result from any such commercial tests or treatments.

Your specimens may be used for future research, even though the purpose of the future research is not known at this time.

PARTICIPANT:
PLEASE INDICATE YOUR CHOICE BY INITIALING ONE (1) OF THE FOLLOWING OPTIONS

___ I consent to have my specimens used for future research studies.

___ I consent to have my specimens used for future research studies only for the study of _____.

___ I do NOT consent to have my specimens used for future research studies. The specimens will be destroyed at the end of the study.

PARTICIPANT:
FOR FUTURE CONTACT, PLEASE INITIAL YOUR CHOICES BELOW

I consent to be contacted in the future to learn about:

_____ New research protocols that I may wish to join.

_____ General information about research findings.

_____ Information about the test on my sample that may benefit me or my family members in relation to choices regarding preventive or clinical care.

_____ I DO NOT AGREE TO BE CONTACTED IN THE FUTURE, EVEN IF THE RESULTS MAY BE IMPORTANT TO MY HEALTH OR MY FAMILY'S HEALTH.

Your wish does not constitute a guarantee that you will be contacted.

CAN I BE ASKED TO STOP PARTICIPATING IN THIS STUDY BEFORE THE STUDY IS FINISHED?

Yes, you can be asked to stop if:

- You are hospitalized.
- You develop severe unexpected complications.
- You fail to follow instructions given to you by the researcher.

MAY I STOP THE STUDY AT ANY TIME?

- Your participation in this study is voluntary and you may withdraw from the study at any time without giving a reason.
- If you agree to participate and withdraw at a later time, some of your information may have already been entered into the study and that will not be removed.
- Your treatment by doctors and staff at the institution(s) involved in this study, now and in the future, will not be affected in any way if you agree to participate and withdraw later.
- Your decision not to be in this research study will not result in any loss of benefits to which you are otherwise entitled.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS RESEARCH STUDY?

- Your participation in this study is voluntary.
- You do not waive any of your legal rights by participating in this research study.
- Your treatment by doctors and staff at the institution(s) involved in this study, now and in the future, will not be affected in any way if you refuse to participate or if you enter the study and withdraw later.

Informed Consent Signature Page

The following is a list of items we discussed about this research study. If you have any questions about any of these items, please ask the person who is discussing the study with you for more information before agreeing to participate.

- What the study is about.
- What I must do when I am in the study.
- The possible risks and benefits to me.
- Who to contact if I have questions or if there is a research related injury.
- Any costs and payments.
- I can discontinue participating in the study at any time without penalty.
- Other choices.
- All written and published information will be reported as group data with no reference to my name.
- I have been given the name of the researcher and others to contact.
- I have the right to ask any questions.

Printed Name of Participant	Signature of Participant	Date
Printed Name of Person conducting the Informed Consent Process	Signature of Person conducting the Informed Consent Process	Date

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