

Healthy Aging
in
Neighborhoods of
Diversity across
the
Life Span

Kidney Function in
Diverse Populations



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Introduction

We must have your written informed consent before we perform research tests or examinations.

We follow federal regulations for research with human subjects. These regulations require us to make sure that you understand what examinations we will perform and the risks that are involved, if there are any.

This booklet reviews the tests of kidney function that will help us study the Glomerular Filtration Rate or GFR for short. We perform these tests free of charge. You should understand the purpose of this study before you agree to participate in this research. We welcome any questions that you might have about what to expect in this study. This is a study related to the HANDLS study, but like all HANDLS tests you may decide that you do not want to have this test done. If you choose not to take these test it will not affect your status as a HANDLS participant. While you are a part of this study we will ask you questions about your emotional and mental health since stress and emotional factors are important in managing and surviving kidney disease and many other diseases of aging. We will ask you questions about health matters to find out if there are things we can do to help people understand illness and ways to prevent getting sick easier. We will also provide health information about kidney

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disease, and information about managing money and meeting household bills.

We want to make sure that you understand the tests in this study. We must witness your signature on the consent form. Please do not sign the consent form until you arrive at the ASTRA Unit at Harbor Hospital.

Purpose of the Study

The purpose of this study is to use the most effective way to accurately measure renal function and identify early kidney disease in racially and ethnically diverse populations. We will directly measure your kidney function or GFR using blood clearance of a drug called Iohexol. Iohexol is a drug that contains iodine that is used in some types of X-rays. In fact you may have already taken this drug also caused a contrast material when you have had certain types of x-rays. It may also be used as a marker of how your kidney filters your blood. This will help us find out the best way to estimate kidney function in people from different racial and ethnic backgrounds. We will study kidney function as well as results from the other tests that are part of HANDLS. We will also try to find out if certain genes give people a higher risk of getting kidney disease. We will also store samples of blood and urine in case other tests become available in the future that will help to diagnose kidney disease.

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For the study you will visit the ASTRA Clinical Unit at Harbor Hospital. We call this part of the Healthy Aging in Neighborhoods of Diversity across the Life Span study: Kidney Function in Diverse Populations (HANDLS-KFDP).

List of Tests

You may participate in some or all of our tests. You may stop any test anytime you want even after you agree to do it.

We want you to understand the risks in taking some of these tests. We welcome your questions about the tests and any risks even after the test starts.

Risks, if any, are stated and discussed with the description of the test, or in the section on Assessment of Risks in this booklet.

Blood, Tissue, and Urine Sampling. If you agree, we will ask you to give us a blood sample and a urine sample. We will use these samples to measure your kidney function so that we can measure changes in your health if we test you again. We will measure blood chemistry that may tell us how well your kidneys work. Women between the ages of 30 and 55 years will get a pregnancy test. Doctors often make new discoveries by testing blood and urine. We would like

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to freeze a portion of your blood and urine samples to save them in our frozen tissue bank. We are not sure what new discoveries will appear in the future. We want to set aside your samples until there are new tests that will help us understand kidney health and aging.

More and more, we are discovering that our genes are important for understanding our health. Your genes are the parts of each cell inherited from your mother and father. Your genes are what make you a unique individual. Genes are made from DNA. We want to use some of your donated blood to freeze your DNA. We are not sure what studies will use your DNA. New studies may look at how your genes affect age-related kidney disease.

Tissue samples saved in our bank will be stored at very low temperatures. Unlike household freezers, these freezers can preserve samples for many years, perhaps many decades. We will label your samples with code numbers. Only researchers in this study will know your code number. Only researchers in this study will know the results of tests using your genes. We will not reveal your results to anyone who is not associated with this research.

We will ask you if you want the results of the tests that we perform on your blood and urine. We will also ask you if you want us to send your results to your per-

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sonal physician. We do not plan to report the results of the studies we do on your genes because we have not learned enough to safely do so. In the future, we may offer you some of the results if the Food and Drug Administration approve some of the tests.

We will ask you to donate about 45 milliliters of blood. For comparison, the Red Cross usually asks for a donation of about 500 milliliters of blood. Forty-five milliliters is equal to 3 tablespoons.

The Kidney Function Test. Prior to arrival For those who agree to participate, we will provide a detailed set of instructions. You will be asked to have a light meal the evening before and a light breakfast at home before you come for the visit. We will review all of your medications with you over the telephone one week before your visit. Some medicines can affect the test of we may ask you to stop taking some of those medicines before coming for your test. Everyone will be asked to drink two to three glasses of non-alcoholic, non-caffeinated beverages prior to coming for the study visit.

Study day. An IV line will be inserted at two different sites. A blood sample will be taken and then 5 ml of the study medicine, Omnipaque 300 iohexol, will be injected into one of the intravenous lines (IV) over a 60 second period. After the medicine is injected, the intravenous line used for injection will be removed.

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Blood samples to measure the amount of drug that is still in your blood stream will be taken at approximately 10, 30, 120, 240, and 300 minutes from the second intravenous line. Participants are free to move around during the GFR test. After the final blood sample, the second intravenous line will be removed; participants will be observed for approximately 30 minutes and will return home.

Diagnostic Interview Schedule. The Diagnostic Interview Schedule is an interview designed to determine if you have ever experienced a mental health condition. It will be given by a trained interviewer and will take about 90 minutes to complete. It will be given while you are waiting to give your blood samples for the GFR measurement test.

Questionnaires. We will ask you to complete several questionnaires about your health, your daily activities, and the jobs you have had and the job you have now. We will also ask about your knowledge of health related terms and instructions, education, family income, and your feelings and interests.

These questionnaires will be filled out during your visit to ASTRA by using a computer and headphones. We will help you do the questionnaires if you want us to. If you have trouble seeing or reading the questions you may ask one of our testers to help you. Some of the tests will be administered by our testing staff as

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well. We will ask about the activities that you enjoy and about your moods and how you feel most of the time.

Statements and Assessment of Risks

Blood Sampling. We want you to know that there are some risks in donating a blood sample. The nurse will insert a needle in a vein in your arm. There is a risk of an infection from the needle puncture. There is also a risk of a black and blue mark, and you may feel faint. These risks are very small. Our nurses are well trained and have drawn blood many times. In over 50 years, no one in our studies has had an infection from donating blood. It is common to have a small black and blue mark, but it disappears after a day or so. Some people have begun perspiring, or they felt nauseated and their pulse slowed. None of them had any after effects.

Insertion of Intravenous Cannula (IV).

If you agree to participate in this study the study nurse or doctor will insert 2 IVs. We will draw blood from one and use the other to administer the drug that helps us to measure how well your kidneys work. Our staff is very experienced in IV placement. The risks for IV placement are very much like those for drawing blood, bruising, bleeding, and infection. Some people

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perspire, or feel nauseated and their pulse slows. These are not common or long lasting problems but they can happen.

Kidney Function test (GFR Measurement)

Exclusion criteria. You cannot be in this study if you have any of the following: reaction to x-ray contrast media; allergy to iodine or iodine-containing substances; current treatment for thyroid carcinoma; acute asthma or chronic obstructive lung disease in the past three months requiring hospitalization or oral steroid therapy; currently undergoing or having received either peritoneal dialysis or hemodialysis treatment within the past three months; solid organ, bone marrow or stem cell transplant; condition causing inability to have insertion of two intravenous catheters; cognitive or physical impairments that will not allow completion of the study.

Iohexol may cause some reactions which are usually mild to moderate in severity but they are generally temporary. Rarely serious, life-threatening or fatal reactions, mostly affecting the heart and blood vessels, have been associated with the iohexol. We are using a low dose of iohexol. When iohexol is used at higher doses, severe events have been reported to occur in less than 1 in 2000 to 1 in 20,000 administrations.

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The injection of contrast media, like iohexol, is frequently associated with a short-lived sensation of warmth and pain. Some patients experience temporary feelings of dizziness or lightheadedness, headaches, abnormal vision nausea, diarrhea, or cramps, anxiety, fever, being unable to move and speak, and convulsion. You may also experience coughing or laryngitis (sore throat). These symptoms are most likely to occur immediately after the iohexol is given. These symptoms are rarely felt. When iohexol is used at higher doses, the chance of a person experiencing any symptom is 1 in 100 to 1 in 1000 administrations. If you experience any unusual symptoms, notify the study nurse or personnel immediately.

If you have a problem, our physician will take care of any minor short-term problems. If you need more advanced hospital treatment, we will evaluate you at Harbor Hospital.

Pregnancy

If you are female, you may participate in this study only if you are certain you are not pregnant. If you become pregnant (or suspect pregnancy) before the study is completed, you must inform the investigator.

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Diagnostic Interview schedule & Questionnaires

We want you to know that some people find these tests tiring. Sometimes, people feel nervous when they do these tests. All examiners who are involved in giving these tests are experienced in using these procedures and they will minimize any discomfort that you might feel. If the tests are disturbing you, then you may stop testing any time you want.

Compensation

As a volunteer, you will receive a monetary honorarium for participating in this study. If you participate in this part of HANDLS you will receive a total of \$100. We will provide round-trip transportation from your home to the National Institute of Aging ASTRA Clinical Research Unit at Harbor Hospital if you want it. We will serve a low protein lunch if you are participating in tests during mid-day. We will do our best to meet your dietary needs if you have any.

You are participating in a research study and our physicians and technicians are not your primary health-care providers. We will provide medical feedback to you and, with your permission, to your personal physician about your health based on the tests in which

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you participate. If you need a referral to a physician, we will provide a list of local physicians.

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