NCI Community Oncology Research Program – Kansas City (NCORP-KC)

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: The National Myelodysplastic Syndromes Natural History Study

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You are being asked to take part in this research study because you have been recently diagnosed with one of the blood disorders included among Myelodysplastic Syndromes (MDS), or are having a bone marrow sample collected to determine if you have a blood disorder called MDS.

What is the usual approach to my condition?

Myelodysplastic syndromes (MDS) are conditions that occur when the blood-forming cells in the bone marrow are damaged and have problems making new blood cells. Many of the blood cells that are made by these damaged cells are not normal. The abnormal blood cells die sooner than normal cells, leaving the person without enough normal blood cells and with low blood counts.

Treatments for you are selected based on the severity of your problems. Treatments may include care to help relieve symptoms (such as transfusions and antibiotics) and/or drugs and stem cell transplants aimed at changing the long-term behavior of your disease.

What are my other choices if I do not take part in this study?

The alternative option is not to participate. Your decision to participate or not to participate in this study will not affect your future treatment. Your participation in this study is voluntary.

Why is this study being done?

We are asking your permission to include you in a research study called The National Myelodysplastic Syndromes (MDS) Study. The purpose of this project is to collect your blood, bone marrow and other tissues (hair follicle (eyebrow hairline sample), and cells from the inside of your cheek (also called buccal cells), and information from you and other patients to investigate how your disease changes over time. This knowledge will allow doctors to better understand how MDS changes over time and may lead to better ways to prevent, detect, and treat MDS.

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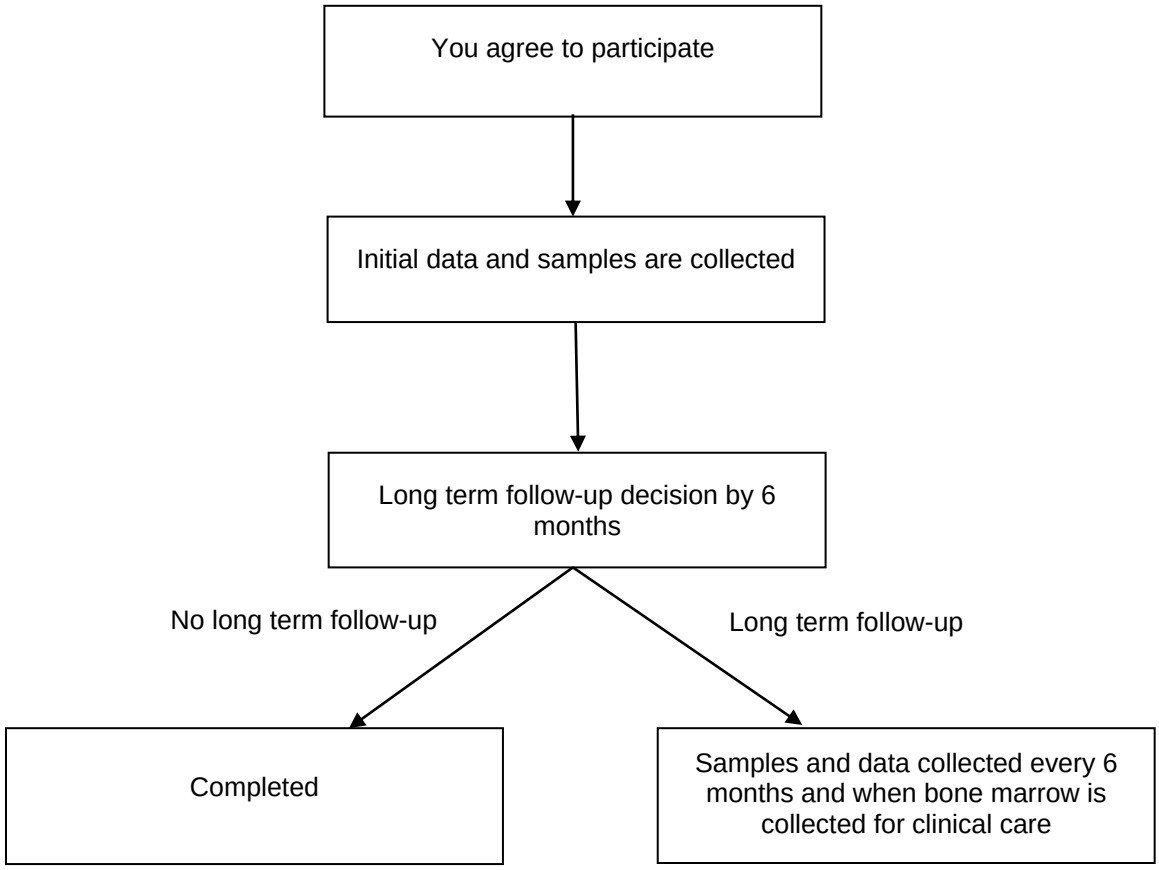
The samples and information collected from you will be used to create a database and central biorepository (a special laboratory where samples are stored) that will be used for future research.

This study is being sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI). The NHLBI and NCI are part of the US government agency known as the National Institutes of Health (NIH).

What are the study groups?

This research study has 1 study group made up of people with low blood counts who are undergoing care for their condition. If you agree to participate, you will be asked to fill out questionnaires about you and your physical and emotional well-being and provide samples of your blood, bone marrow, and other tissues for research lab tests. We are also asking for your permission to collect information from your medical records. Depending on your disease status, we may stop collecting data and samples after your first study visit.

Another way to find out what will happen to you during the study is to read the chart below.



How long will I be in this study?

All patients who agree to be in the study may be followed for life. Information for the study will be collected during office visits, by phone, by mail, or by medical record review. This will occur every 6 months.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures are part of your usual care. However, there are some extra tests, surveys and/or procedures that you will need to have if you take part in this research study.

You will have the following tests and/or procedures if you decide to participate in this research study:

When you begin the study

- Your doctor will ask you about your health and your disease, including what treatments you have already had for your disease.
- You will have a physical exam, including checking your body for signs and symptoms of MDS.
- Blood, bone marrow, eyebrow hairs (or hairs from the hairline) and cells from the inside of your cheek (also called a buccal swab) will be collected.
- You will be asked to complete questionnaires that take approximately 20-25 minutes to fill out.

During the study

- Several types of specimens will be collected: 1) Blood, about 2 1/2 tablespoons of blood will be needed at each sampling point. These samples will be collected when you have having blood taken for your routine care. 2) Bone marrow, about 2 1/2 teaspoons will be collected at the same time you are having bone marrow collected 3) Optional eyebrow hairs (or hairs from the hairline), buccal (inside the cheek) swab at 12 and 24 months after the start of the study.
- You will be asked to complete questionnaires at 6 and 12 months after the start of the study and then every year. The questionnaires take approximately 20-25 minutes to fill out

The blood and bone marrow for this study may be collected at the same time these samples are collected as part of your usual care.

We are asking your permission to store your blood, bone marrow, eyebrow hairs, buccal swab, or skin for future research projects. The samples will be stored at a Biobank (a laboratory at H. Lee Moffitt Cancer Center in Tampa, Florida) and when the study ends, the samples will be sent to the National Heart, Lung, and Blood Institute where they will be kept for future research projects.

The purpose of sending your blood samples to the Biobank is to make samples available for future researchers including some who are not involved in this study. Only qualified researchers from non-profit or for-profit groups can submit a request to use the materials stored in the Biobank. A committee of experts at NHLBI will review each request to use the samples for research. All research projects using these samples will be reviewed by an ethics or institutional review board to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.

Neither you nor your study doctor will be notified when research will be conducted or given regular reports or other information about any research that is done using your samples.

Your diagnosis will be confirmed by Biobank doctors who may share their findings with

your doctor.

Results from the research may be placed in central storage systems called databases. It is possible that some of your genetic and health information may be placed in these databases. It is also possible that some of these databases may be public. If done, your identity will not be revealed.

DNA (your unique genetic material) from your stored blood samples might be looked at in a process called genome sequencing. Genome sequencing is a laboratory process that includes looking at all the individual genes in your DNA. Body tissues are made up of cells. Cells contain DNA, which is your unique genetic material that carries the instructions for your body's development and function. Your tissue samples may be used to determine the sequence of some or all of your genes (DNA).

DNA from your stored blood samples might also be used in genome-wide association (GWA) studies. Genome-wide association studies are a way for scientists to find genes that have a role in human disease or treatment. Each study can look at millions of genetic changes at the same time.

If your samples are used in such a study, the researcher is required to add your test results and sample information into a shared, public research database. This public database is currently managed by the National Center for Biotechnology Information (NCBI). It is very unlikely that the NCBI could identify you, or link you to your information or research samples.

What are the possible risks in providing your samples for research?

The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. Infection is rare, but could occur. If you are uncomfortable at the sight of blood, you may feel light-headed or faint. The blood collected for this study will usually be collected at the same time blood is being collected as part of your usual care.

The eyebrow hair collection may result in brief pain and temporary redness and/or swelling around the area of collection.

The bone marrow collection may result in bleeding, bruising, or discomfort at the puncture site. During the procedure, you may feel a sting and slight burning sensation when the numbing medicine is applied. You may feel pressure as the needle is inserted and possibly a sucking sensation as the marrow is removed. This feeling lasts for only a few seconds. Some patients find this procedure uncomfortable or painful. Serious bleeding or infection are rare, but could occur. The bone marrow for this study will be collected at the same time bone marrow is collected as part of your usual care when medically necessary. You will not be required to undergo a separate procedure to collect bone marrow samples for this study.

When my samples are used for research, how will information about me be kept private?

Your privacy is very important to the researchers and they will make every effort to protect it.

Here are a few of the steps they will take:

- When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code.
- The list that links the unique code to your name will be kept separate from your sample and health information.
- Researchers to whom NHLBI sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
- Information that identifies you will not be given to anyone, unless required by law.
- If research results are published, your name and other personal information will not be used.

What possible risks can I expect from taking part in this study?

If you choose to take part in this research study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual to provide samples or complete study questionnaires.
- You may be asked sensitive or private questions which you normally do not discuss.

Let your study doctor know of any questions. You can ask the study doctor questions at any time.

There is a risk that someone could gain unauthorized access to the data that is stored about you. In some cases, it could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. We believe the chance these things will happen is very small, but we cannot make guarantees.

There is a risk that someone could trace the information in a scientific database back to you. Even without your name or other identifiers, your genetic information is unique to you (like a fingerprint). We believe the chance that someone will identify you is very small. But the risk may grow in the future if people come up with new ways of tracing information.

What possible benefits can I expect from taking part in this study?

This research study is unlikely to help you. This research study may help us learn things that may help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible. The study doctor contact information is noted in the section below. If you decide to stop, you will not lose any rights you normally have, you will still have the same health care benefits, and you can continue getting care from your doctor. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you no longer provide samples and data
- If the study is stopped by the sponsor or Institutional Review Board (IRB)

What if I change my mind about allowing my samples to be used for research?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. No additional health information will be collected. Samples or related information that have already been given to or used by researchers will not be returned. Available samples that have not been distributed will be destroyed if requested in writing.

What are my rights in this study?

Taking part in this research study is your choice. No matter what choice you make, and even if you change your mind, there will be no penalty to you. You will not lose medical care or any legal rights. Health insurance companies and group health plans will not be provided access to your data from this study.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal

for health insurance companies and group health plans to discriminate against you based on your genetic information.

Health insurance companies and group health plans will not be provided access to your data from this study. This means that they must not use your genetic information when making decisions regarding insurability. Be aware that this new federal law will not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

For questions about your rights while in this study, call the NCI Community Oncology Research Program – Kansas City Institutional Review Board at 913-948-5588.

What are the costs of taking part in this study?

You and/or your health plan/insurance company will need to cover all of the costs, including the cost of tests, procedures, or medicines to manage any side effects of tests performed as part of usual MDS care. You should contact your insurance company to get information about what costs they will cover. There are no costs to you or your insurance for the collection of samples for this study or the future research. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this research study and need medical treatment, please tell your study doctor. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for research related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a research study.

Who will see my medical information?

Your privacy is very important and the researchers make every effort to protect it. Your information may be given out if required by law. Some of your health information, and/or information about your specimens, will be kept in a central database for future research. No identifying information is maintained in the database.

The National Heart, Lung, and Blood Institute (NHLBI), the custodian of collected tissues and data, is conducting this study in collaboration with the National Cancer Institute and ECOG-ACRIN Cancer Research Group. Your doctor is a member of ECOG-ACRIN or another group that is participating in this study. You may visit the ECOG-ACRIN Web site at http://ecog-acrin.org/ for more information.

To help protect your privacy, ECOG-ACRIN has obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, ECOG-ACRIN cannot be forced to disclose information that may identify you in any federal, state or local civil, criminal, administrative, legislative or other proceeding. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, data center and central laboratory staff
- The Institutional Review Board, IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study
- The National Institutes of Health

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on https://ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ (*insert name of study doctor[s]*) at _____ (*insert telephone number*).

Release

By signing this form you authorize NCORP-KC to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

You will get a copy of this form. If you want more information about this study, ask your study doctor.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the study.

Participant _____

Participant's signature _____

Date of signature _____

Person obtaining consent _____

Signature of person obtaining consent _____

Date of signature _____