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

Study Title for Study Participants: A Simplified Patient Care Strategy to Decrease Early Deaths in Acute Promyelocytic Leukemia (APL):

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: A Simplified Patient Care Strategy to Decrease Early Deaths in Acute Promyelocytic Leukemia (APL)

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What is the usual approach to my acute promyelocyctic leukemia (apl)?

You are being asked to take part in this research study because you have been diagnosed with Acute Promyelocytic Leukemia (APL). The established treatment for APL is chemotherapy drugs that are highly effective but also complicated. Since APL is very rare, doctors may have less experience treating this type of blood cancer and managing the complications. This study is directed at co-managing patients by discussing between APL expert and treating physician.

What are my Other Choices if I Do Not Take Part in This Study?

You do not have to be in this study to receive treatment for APL. Your study doctor will inform you of your treatment options whether or not you decide to participate in this study.

Why is this study being done?

APL is a highly curable leukemia with most large clinical trials showing a survival above 90%. These trials are conducted in experienced centers on a protocol. However, APL is an uncommon disease and doctors who are not routinely involved in taking care of APL patients in smaller centers as well as in larger treatment centers, may not be familiar with the treatment or expected complications. In recent years, results from several centers and countries showed that 1 in 3 (30%) patients diagnosed with APL die within the first month of diagnosis from complications. These deaths are most often from bleeding, infections, and complications from drugs. It may be possible to prevent many of these deaths if these complications are prevented, recognized early and treated aggressively. The patients who survived the first month had an excellent quality of life with a low chance of relapse and treatment related complications.

We developed a set of simple guidelines based on recommendations from experts and used them in a preliminary trial that resulted in a marked decrease in early deaths. The guidelines

when used with advice from APL experts by phone or email decreases complications and deaths further.

The purpose of this study is to see if implementing our APL guidelines along with support from APL experts will decrease deaths and improve survival. In addition data will be collected from patient medical records and maintained on a database. This information will help us understand if the guidelines have been followed and the effect on preventing complications and death. It will also allow us to learn more about APL treatment, based on the care you received.

The goal is to decrease early deaths by using the guidelines we developed as well as your doctor communicating with experts who have more experience in treating APL.

What are the Study Groups?

All patients enrolled in the trial will be a part of the study group.

How Long will I be in This Study?

Your information will be collected for entire duration of the study which is 5 years.

How many people will take part in this study?

About 200 people will take part in this study.

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

There are no risks in following the standard treatment guidelines and consulting with an expert. Data will be collected from the medical record and stored in a database. Therefore, the risks for this study could include accidental loss of your information or the risk of unauthorized personnel accessing your information. Security precautions will be taken to make sure your information is collected, and stored securely, and is password protected. It will be accessible only by the people directly involved in the study.

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

Although there may not be any specific benefits to you for taking part in this study, your participation will allow researchers to learn even more about APL. Discussions regarding your care with an APL expert can help lead to better outcomes which is the goal of this study.

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 so you can stop safely. 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. But your doctor can still consult with the APL expert.

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 do not follow the study rules
- If the study is stopped by the sponsor or IRB.

What are my rights in this study?

Taking part in this research study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Central Institutional Review Board at 888-657-3711.

What are the costs of taking part in this study?

You will not receive any payment for being in this research study nor will it cost you any money to participate.

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 offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for research study-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 to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

The ECOG-ACRIN Cancer Research Group is conducting this study. ECOG-ACRIN is a cancer research group that conducts studies for the National Cancer Institute. Your study

doctor is a member of ECOG-ACRIN or another group that is participating in this study. 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 (for example, by court subpoena) 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:

- ECOG-ACRIN Cancer Research Group
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The National Cancer Institute in the U.S.

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 http://www.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's signature

_____

Date of signature _____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature _____