Study Title for Study Participants: Impact of Cancer on Employment and Finances

Official Study Title for Internet Search on https://ClinicalTrials.gov: EAQ162CD Longitudinal Assessment of Financial Burden in Patients with Colon or Rectal Cancer Treated with Curative Intent (NCT #03516942)

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Why is This Study Being Done?

The purpose of this research study is to better understand the impact of cancer treatment on a patient's employment and finances. This study will also help describe what different resources (i.e. social worker, financial counselor) were available during your treatment for either colon or rectal cancer.

You are being asked to take part in this research study because you have been diagnosed with colon or rectal cancer. Treatments for cancer can impact people's ability to work and their finances. In this study you will be asked to fill out questionnaires related to how cancer affects your employment and finances. In addition, you will be asked what resources are available to you at your cancer center.

There will be 563 patients taking part in this research study.

What is the usual approach to the use of medical information for research?

In order to obtain medical information from patients, hospitals and doctor's offices typically use a "release of medical information" form. In this study, the consent form describes what type of information we want to collect from your medical records. By signing this consent form, you give us permission to use this information from your medical records along with your answers to the questionnaires for research.

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

Participation in this study is optional. People who do not take part in this research study will continue to receive recommendations for the treatment and follow up for their cancer. If these treatments were to impact your employment or finances, your doctor can have you speak to someone such as a social worker or financial counselor.

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?

You will be in the study for 24 months (2 years). You may stop participating at any time. However, we encourage you to talk to your doctor before you decide to stop participating in the study.

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What is involved and what will happen in this study?

You will be asked to complete questionnaires at 5 time points over 24 months. A caregiver may assist you with completing the questionnaires if you prefer. At the time of registration to the study, you can choose to receive the questionnaires either on paper or via the internet using your computer or mobile device (i.e., phone, tablet). We will provide you with the questionnaires within 60 days of your cancer diagnosis and then at 3, 6, 12, and 24 months after your cancer diagnosis. We ask that you complete and return them as soon as possible after receipt. We estimate that it will take 45-60 minutes to complete the first questionnaire and then between 20 and 30 minutes to complete the questionnaires at 3, 6, 12, and 24 months.

In addition to information about your finances and employment from the questionnaires, we will also obtain the following information from your medical records:

- Basic information about you, including your name, sex, ethnicity, telephone number, birth date, home address and email address
- Information on your cancer and treatment plan
- Your health insurance status

You will be asked to provide your contact information to the ECOG-ACRIN Outcomes and Economics Assessment Unit (OEAU) located at Brown University, which will administer the surveys. If you would like to complete the surveys online, you will need to provide an email address and date of birth in order to activate an online account for completing the surveys. If you have e-mail and internet access, you will receive e-mail communications from the OEAU to help you set-up an on-line account that you will use to complete surveys.

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

Participation in this study will require you to complete 5 study questionnaires. These questionnaires would not have to be completed if you choose not to participate in the study.

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

The nature of this study is to answer questions pertaining to the impact of your cancer and treatments on your employment and finances. This study is not expected to produce any serious adverse events or risks to you. Completing the questionnaires may remind you of unpleasant aspects of your condition and treatment, which may be upsetting. As some of these questions may be of a sensitive or private nature, you are free to either complete the surveys independently or to not answer the question(s). In addition, there is a risk, especially

if completed online, that your information will not be private. Your privacy, however, is very important to us and we make all efforts to insure that all information enter cannot be identified to you. The online survey system uses technology to encrypt all information that is collected.

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

If you agree to take part in this study, it is unlikely to have any medical benefits to you.

We hope that information you provide will help us better communicate with future patients about the impact of cancer and treatment on work and finances.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. Participation in this study is voluntary and you may discontinue participation without penalty or loss of benefits to which you may be otherwise entitled. If you choose to withdraw from this study, we will use the information collected unless you specifically ask us not to. Upon notification and verification of withdrawal, we will make no further attempts to collect survey data from you.

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 _____ (insert name of center) Institutional Review Board at _____ (insert telephone number).

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What are the costs of taking part in this study?

There are no costs to taking part in this study. Questionnaires will be completed online or on paper. If you need assistance with the questionnaires, you will be provided with a toll-free phone number. If you are completing the questionnaire on paper at home and sending it through the mail, you will be provided with pre-addressed and stamped envelopes.

You will not be paid for being in this study.

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 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:

- The study sponsor supporting the study
- 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 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).

My signature agreeing to take part in the main 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 main study.

Participant's signature

_____

Date of signature _____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature _____