

Study Information

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Every year, an estimated one million Americans participate in clinical trials to help researchers gather important information about the benefits and risks of new drugs and treatment methods. In recent surveys, the majority of these participants reported receiving excellent care and viewed their participation as a positive experience. Thanks to patients enrolled in clinical trials, researchers have been able to identify new and effective treatments for various types of cancer. These treatments have the potential to become the new standard of care offered to future patients.

ACRIN Study Participation

You are being asked to take part in this study because you have been diagnosed with prostate cancer and have enrolled in a study designed by Phillip Febbo, MD, a cancer researcher at Duke University. As part of this study you are receiving the drug dasatinib for your treatment.

The ACRIN study is evaluating an imaging test called a PET scan using the tracer drug 18F-fluoride. Twenty-four participants who are receiving dasatinib in Dr. Febbo's study will also be enrolled in the ACRIN imaging study.

Why Is This Study Being Done?

The purpose of this study is to learn if the images provided by an 18F-fluoride PET scan can help doctors determine if the dasatinib is making any changes to normal bone or diseased bone. The information gained from the 18F-fluoride PET scan will be compared to other standard ways doctors evaluate the effectiveness of a cancer therapy drug. They hope to learn if the images from 18F-fluoride PET scan provide doctors with better information for identifying bone cancer.

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A Prostate Cancer Study

Learning if a PET scan can help evaluate prostate cancer that has spread to the bone



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AMERICAN COLLEGE OF
RADIOLOGY
IMAGING NETWORK

Funded by the National Cancer Institute

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Frequently Asked Questions

■ What am I being asked to do in the study?

If you agree to take part in this study, you will have the following procedures:

- Two (2) PET scans with 18F-fluoride given through an IV
- You will have one (1) 18F-fluoride PET scan within 7 days before starting treatment with dasatinib for your prostate cancer
- You will have one (1) 18F-fluoride PET scan approximately 12 weeks after you have your first dasatinib treatment.

■ Who can take part in this study?

Inclusion Criteria

You can take part in the ACRIN study if you:

- Are enrolled in Dr. Febbo's study
- Are age 18 years or older
- Have prostate cancer that has spread to the bone
- Have testosterone levels specified for the study
- Willing to undergo 2 PET scans about 12 weeks apart.

Exclusion Criteria

You can not take part in the ACRIN study if you:

- Have a serious condition that would keep you from getting treatment and imaging scans
- Have extremely poor IV access
- Had treatment to your bone less than 4 weeks from the date of your first PET scan
- Are unable to lie still for the imaging
- Weigh more than 300 lbs.

■ How long will I be in the study?

You will be involved with this study's imaging procedures for about 16 to 18 weeks. Each PET imaging visit will require about two to three hours of your time.

In addition, study doctors will review your medical records for up to 5 years to compare the results of the PET scan with the course of your cancer. The 18F-fluoride PET scans in this study will be taken before and after your dasatinib treatment.

■ What are the side effects of the study?

All participants will be carefully watched for any side effects as a result of the 18F-fluoride PET scan. Any side effects are usually mild. Talk to your doctor or nurse about any possible side effects at your initial consultation.

■ Are there benefits to taking part in the study?

This is not a treatment study and you are not expected to receive any direct medical benefits from your participation. The information learned from this study may lead to better treatment in the future for patients with prostate cancer.

■ Will I Have To Pay For Anything?

Taking part in this study will not add costs to you or your insurance company. Many of the tests and procedures performed as a part of this study are routine for patients with prostate cancer and will be charged to your insurance company in the usual manner. You may be responsible for co-payments and deductibles that are standard for your insurance coverage. ACRIN will pay for the two PET scans with 18F-fluoride as part of the study

■ What are my rights if I choose to take part in this study?

Taking part in this study is voluntary and you may choose to stop at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care.

■ 18F-fluoride PET (Positron Emission Tomography)

PET is a nuclear medicine imaging scan that produces 3-D images (pictures) that provide information about cell function and show the difference between healthy tissue and diseased tissue. 18F-fluoride is a new tracer used during a PET scan that is being evaluated to help doctors learn if dasatinib makes any changes to your bone.

"The quest for effective imaging is a critical challenge in metastatic prostate cancer. This study is an important effort to look at a new imaging agent that may provide valuable information on bone metastasis."

— Missy Layfield
Thoracic Committee, Patient Advocate