A Study to Evaluate a Method for Tracking Breast Cancer That Has Spread to the Bones

STUDY TITLE: 18F-Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET/CT) for the evaluation of response to therapy in bone-dominant metastatic breast cancer

TRIAL NUMBER: NCT01996046

FOCUS: Diagnostic

WHAT HAPPENS IN THIS STUDY?

This study's goal is to test whether an imaging method called Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET/CT) – FDG PET/CT – can visualize and measure response to hormone therapy for women with breast cancer that has spread, or metastasized, to the bone.

This is an observational study, which means participants will not be assigned to a specific treatment group. Rather, all participants will receive hormone therapy as part of their routine care. Participants will have FDG PET/CT scans as part of the study before starting a new breast cancer hormone therapy, as well as at one month and three months after starting treatment.

ARE YOU ELIGIBLE?

A woman may be eligible for this study if she is over age 18, has a history of estrogen receptor positive (ER+) breast cancer with bone metastases and is planning to start a new hormone therapy for her breast cancer.

The status of this study is subject to change. To see the most current information, visit clinicaltrials.gov.

WHAT WILL THIS MEAN FOR PATIENTS?

It is difficult to measure how bone metastases respond to therapy using current methods. The researchers hope to see if FDG PET/CT is helpful as an early treatment monitoring tool for women with bone metastases. If successful, this trial may offer an improved way to assess whether bone metastases are responding to treatment and to inform treatment decisions.

WHO DO I CONTACT ABOUT THIS STUDY?

LEAD TRIAL PI AND TRIAL LOCATION:

Amy Clark, MD, MSCE (PI); David Mankoff, MD, PhD (Co-PI), Hospital of the University of Pennsylvania (HUP), Philadelphia, Pennsylvania, United States

STUDY CONTACT INFORMATION:

Erin Schubert, 215-573-6569, erin.schubert@pennmedicine.edu or Theresa Berger, 215-746-2813, Theresa.Berger@Pennmedicine.upenn.edu

KOMEN CONNECTION

Amy Clark, MD, MSCE, the Principal Investigator of this study, holds a Komen Career Catalyst Research grant focused on novel breast cancer treatments, including the use of PET to help guide therapy. David A. Mankoff, MD, PhD, the co-Principal Investigator of this Komen funded study, is a Komen Scholar from the University of Pennsylvania. With Komen's support, Dr. Mankoff is studying the use of imaging to measure the metabolism of breast cancer cells to better predict tumor behavior, identify more individualized and effective therapies, and improve our understanding of drug resistance.

BREAST CANCER CLINICAL TRIAL INFORMATION HELPLINE

Call our clinical trial information helpline at 1-877 GO KOMEN (1-877-465-6636) or email at clinicaltrialinfo@komen.org to talk with a trained specialist. Our caring and trained staff provide support and education about clinical trials to help people gain a better understanding of clinical trials.

Amy Clark, MD, MSCE

"The results of this study will inform the design of cutting-edge PET imaging studies and help guide the use of FDG PET for breast cancer patients with bone metastases. Early study results have already contributed to the design of larger national trials on this same topic. We are grateful to Komen for their support of this and other studies at Penn designed to develop and implement imaging tools to help direct more effective treatment of breast cancer, especially metastatic breast cancer."

-David Mankoff, MD, PhD

David Mankoff, MD, PhD

Susan G. Komen®

KOMEN.ORG
1-877-GO KOMEN