

PET is a nuclear medicine imaging technique that produces a 3D image of functional processes in the body. A CT scanner is a special kind of x-ray machine that sends several beams at the same time from different angles; the computer-processed results are displayed on a monitor as a 2D picture.

Many PET scanners also include a CT scanner, which allows images of both anatomy and function to be taken during the same exam. By fusing together information about the size and shape of abnormal cells with information about how they function, the FDG-PET/CT scan provides the most complete assessment of cancer cell function and location.

“Clinical Trials are so important in advancing research and finding new therapies. In early phase trials especially, patients enroll to help future patients. ACRIN 6685 is a rewarding trial to participate in because the results of the combined FDG-PET/CT scan may be helpful in improving the surgical outcome.”

— Neal Levitan
ACRIN Patient Advocate

Principal Investigators

Study Chair
Val J. Lowe, M.D.
Mayo Clinic
Rochester, MN

Study Surgical Co-Chair
Brendan C. Stack, Jr., M.D., F.A.C.S.
University of Arkansas for Medical Sciences
Little Rock, AR

QOL/Cost Data Co-Chair
Christopher S. Hollenbeak, Ph.D.
Penn State College of Medicine
Hershey, PA

Administrative Headquarters

American College of Radiology Imaging Network
1818 Market Street, Suite 1600
Philadelphia, PA 19103
(215) 574-3183

For questions please contact:

Biomedical Research Foundation Center for Molecular I

A Study for Patients with Head and Neck Cancer

Evaluating FDG-PET/CT scans for improved patient
care and quality of life



ACRIN[™]
AMERICAN COLLEGE OF
RADIOLOGY
IMAGING NETWORK

Funded by the National Cancer Institute

Study Information

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

Your doctor has asked you to join in this study because you have recently been diagnosed with head and neck cancer and the surgical removal of lymph nodes in your neck is being considered. This study involves an imaging technique that combines two types of scans: positron emission tomography (PET) and computed tomography (CT).

FDG-PET/CT Scans

Fluorodeoxyglucose (FDG) is an imaging agent that is used with the PET scan in this study. The PET/CT can pick up where FDG creates "hot spots" from within the cancer cells. Doctors hope to find out if FDG-PET/CT tells us more information about a head and neck cancer tumor, especially whether it has spread to the lymph nodes in the neck, rather than the current method of relying on physical examination, MRI or CT scans, or surgery alone. Researchers will then evaluate if the results of the FDG-PET/CT scan changed the surgeon's treatment plan and how that affected your quality of life.

Frequently Asked Questions

Who can take part in this study?

You may be eligible for this study if:

- You are at least 18 years of age
- You have been newly diagnosed with head and neck cancer
- Surgical removal of lymph nodes from your neck is being considered as part of your treatment
- A CT scan or MRI scan within the 4 weeks before enrollment confirms the diagnosis of head and neck cancer
- The cancer has not spread to the lymph nodes in your neck
- You are at high risk for neck metastasis because you have one of the following types of head and neck cancer:
 - Oral cavity cancer
 - Oropharynx cancer
 - Larynx cancer
 - Supraglottic cancer

Who cannot take part in this study?

You cannot join this study if:

- You are pregnant and/or breastfeeding
- You have sinonasal, thyroid, or nasopharyngeal cancer
- You have a tumor of the head and neck other than squamous cell cancer
- You have a salivary gland malignancy
- You have diabetes that is poorly controlled
- You weigh more than 350 lbs

What happens if I choose to join this study?

If you enroll in this study a study nurse or doctor will discuss study details with you including:

- Questionnaire completion
- Tissue sample storage

Standard medical care for your type of cancer includes a diagnostic MRI or CT scan and surgery to remove lymph nodes from your neck. As part of being in this study, the following additional procedures will be performed:

- One PET/CT scan with FDG before your neck surgery
- Checking of glucose levels before the FDG PET/CT scan

You will also be asked to provide a blood sample. This is an optional procedure. The blood samples collected will be stored and used for this study and for future research to learn more about this and other diseases. If you agree to this option, the following procedure will be performed:

- One tube of blood will be taken from the IV catheter placed in your arm for the FDG administration.
- All your personal information will be removed from the sample before it is shared and stored.

After having the FDG-PET/CT scan, you will undergo neck surgery. The surgical removal of lymph nodes from your neck is not part of this study. It is the usual treatment for your kind of head and neck cancer. However, your doctor will take into account the results of the research FDG-PET/CT image to decide how extensive this surgery needs to be.

How much time will the appointment take?

The entire FDG-PET/CT scan procedure is expected to take approximately 2 hours from the time of the FDG injection. This includes time for the blood draw which again is optional.

How long will I be in this study?

You will be actively involved in the study for more than 2 years. Following your neck surgery, you will follow up with your treating doctor at regular intervals, and information will be forwarded to the study doctors until the end of the study. In addition, you will receive a form in the mail with questions about your health. This form will be mailed to you at 30 days, one year and two years after your surgery. The information you provide will help researchers better understand any benefits of the FDG-PET/CT scan.

Are there possible side effects?

All participants will be carefully watched for any side effects as a result of the FDG-PET/CT scan. Side effects are usually mild. Your doctor or nurse will discuss any possible side effects in more detail at your initial consultation.

What are the benefits of participating in the study?

Taking part in this study may or may not improve your health. The results from the FDG PET/CT scan, which will be given to your surgeon before your surgery, may affect decisions about the extent of the surgery needed to remove possible cancerous lymph nodes in your neck. The information and knowledge gained from this study could also help doctors decide on the best treatment for people with head and neck cancer in the future.

What are the costs of taking part in this study?

The cost of a pre-surgical head and neck FDG-PET/CT scan is covered by most insurance companies; however, it is not guaranteed. Please ask your study doctors about any expected added costs or insurance problems. The study will reimburse your institution for the cost of the study imaging procedure if it is not covered by your insurance company.

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

Study participation 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.