As one of the five research groups in the National Cancer Institute’s (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on gender-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types.

NRG Oncology’s extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI.

To contact NRG Oncology, call 267-519-6630 or email info@nrgoncology.org.

NRG Oncology Clinical Trial: NRG-HN006
Randomized Phase II/III Trial of Sentinel Lymph Node Biopsy Versus Elective Neck Dissection for Early-Stage Oral Cavity Cancer
NCT04333537

About the trial
NRG-HN006 is a clinical study that seeks to determine if patient-reported neck and shoulder function and related quality of life is better six months after surgery using Sentinel Lymph Node (SLN) biopsy compared to Elective Neck Dissection (END) for treatment of early-stage oral cavity squamous cell carcinoma (OCSCC) (clinical stage T1-2N0). People with this form of cancer sometimes have metastases (cancer cells that have spread to other parts of the body) that are not visible on imaging scans. Because of this, END is the usual treatment for the disease during which many of the lymph nodes of the neck are removed. Doctors then examine the lymph nodes for metastases to see if additional treatment, such as radiation and chemotherapy, should be given to reduce the chances of the cancer returning. However, 70-80% of patients who undergo END do not have cancer in their lymph nodes. Thus, many people with localized disease are exposed to potential neck and shoulder problems related to the END procedure. SLN biopsy may be a less invasive surgical method for assessing metastasis because it removes a smaller number of lymph nodes from the neck as it uses an imaging agent to see which lymph nodes are most likely to have cancer. Therefore, SLN biopsy could potentially decrease neck and shoulder discomfort and related quality of life issues compared to the experiences of people who undergo END, and this is the primary reason for the study. Another equally important reason to perform this study is to determine if people who receive SLN biopsy experience the same amount of time without the cancer returning as people who have END.

Does Sentinel Lymph Node Biopsy improve survival outcomes when compared to Elective Neck Dissection for early stage oral cavity cancer?
Frequently Asked Questions

What is a clinical trial?
Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?
Men and women 18 and older, who have a proven diagnosis of squamous cell carcinoma of the oral cavity and who are candidates for surgical intervention with SNL biopsy, complete neck dissection, or END, may be eligible for the study.

Can I change my mind if I choose to take part in this study?
Yes. Taking part in this study is voluntary. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

What are the possible study treatments?
If you decide to take part in the study and your PET/CT scan shows that your cancer has not spread, you will be randomly assigned to one of two groups. If your imaging scan shows that your cancer has spread, you will not be able to participate in the study and your doctor will discuss other treatment options with you.

Patients assigned to Group 1 will have SLN biopsy. This involves the injection of an imaging agent in the tumor that follows the lymph system to the lymph nodes in your neck. You will then receive two imaging scans, a Planar and a SPECT/CT. The scans take about 1 to 2 hours and show the lymph nodes where the cancer may have spread (called sentinel lymph nodes). The surgeon will then remove only the sentinel lymph nodes. Patients assigned to Group 2 will receive END surgery, the usual approach to treating your cancer, during which the surgeon will remove many of the lymph nodes in your neck and they will be tested for cancer.

How long will I be in this study?
After either SLN biopsy or END surgery, the doctor will talk to you about the need for additional treatment such as radiation or radiation plus chemotherapy, depending on whether cancer was found in your lymph nodes. If you had SLN biopsy and cancer was found, you will have another surgery called a complete neck dissection to remove many of the neck lymph nodes. Your doctor will assess you in the clinic at 3 weeks after surgery, then every 3 months for the first year, then every 4 months for the second year, then every 6 months for the third year, then yearly for your lifetime.

Are there side effects?
There may be some. There is a risk that the SLN biopsy may not be the same as END at delaying time without cancer. The physical side effects of both procedures are similar and may include: leakage of lymph fluid into the neck; nerve injury and shoulder movement problems; swallowing difficulty; lung infection; bleeding. The SLN biopsy uses an injected imaging agent to see the lymph system and this may cause pain or irritation at the injection site. Your doctor will review all of the potential side effects with you.

More Information
Visit the National Cancer Institute website at https://www.cancer.gov for more information about studies or general information about cancer. You may also call: 1-(800)-4-CANCER (1-800-422-6237).