The Use of 124-I-PET/CT Whole Body and Lesional Dosimetry in Differentiated Thyroid Cancer

NCT03841617

Status	RECRUITING
Phase	Phase 2
Sponsor	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Enrollment	30 participants

Plain Language Summary

This study is using a special type of PET scan with radioactive iodine (I-124) to precisely measure how much radiation a thyroid cancer patient's tumors will absorb before and during radioactive iodine therapy, helping doctors plan more personalized and accurate treatment doses.

You may be eligible if...
- You have been diagnosed with thyroid cancer and had your thyroid surgically removed (with or without lymph node removal)
- You have known persistent, recurrent, or metastatic thyroid cancer seen on imaging (ultrasound, CT, or MRI)
- You are being evaluated for or are already receiving radioactive iodine therapy
- Your cancer shows signs of possibly responding to radioactive iodine (based on blood markers or tumor features)

You may NOT be eligible if...
- Your thyroid cancer does not absorb radioactive iodine (RAI-refractory disease)
- You have conditions that prevent safe use of radioactive iodine
- You are pregnant or breastfeeding

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (10)

- Patients with established thyroid cancer diagnosis based on the pathology report reviewed at the National Institutes of Health, who:
- underwent total thyroidectomy plus or minus neck lymph node dissection as clinically indicated,
- are presenting with known per structural imaging (US neck, CT or MRI neck/chest/abdomen/pelvis) persistent/recurrent disease either locally advanced or presenting with distant metastases; or
- are presenting with suspected persistent/recurrent locoregional or distant metastases based on the high risk features such as advanced tumor per pathology report (tumor size \>4 cm, exrathyroidal extension, higher risk pathology such as tall cell, columnar cell, poorly differentiated variant, follicular thyroid cancer with gross vascular invasion, positive margins after the surgery, bulky lymphadenopathy in the central and/or lateral neck), detectable/increasing baseline/suppressed thyroglobulin (Tg) level or detectable/increasing anti-Tg antibody titers if anti-Tg antibodies are present.
- are either RAI -naive or requiring repeated RAI therapy for locally advanced disease or distant metastases or underwent therapy with BRAF inhibitor (dabrafenib or vemurafenib*) or selumetinib** for at least 4 weeks that may re-induce RAI uptake.

... and 5 more (see full listing online)

Exclusion (5)

- Patients with RAI-non avid disease documented by negative post-therapy whole body scans performed after previous RAI treatments and not subjected to re-differentiation therapy.
- Serious underlying medical conditions that restrict diagnostic testing or therapy such as renal failure, congestive cardiac failure or active coexisting non-thyroid carcinoma, severe depression which might be exacerbated by thyroid hormone withdrawal.

• Patients with spinal or brain metastases as they are at risk of TSH-stimulation induced swelling of metastatic lesions leading to potentially detrimental side effects. These patients will be evaluated per the standard of care protocol 77-DK-0096.

• Pregnant or lactating women per self report.

• Adults who are incapable of providing informed consent.

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States