Validation of ICG-99mTc-nanoscan as Hybrid Tracer for Sentinel Node Biopsy

NCT06666634

Status	RECRUITING
Phase	Not Applicable
Sponsor	The Netherlands Cancer Institute
Enrollment	29 participants

Plain Language Summary

This study is testing a new imaging tracer called ICG-99mTc-nanoscan that combines two types of dye — one visible under special light and one detectable by a radiation scanner — to help surgeons find and remove the first lymph node that cancer may have spread to (called a sentinel node). The goal is to see whether this combined tracer works as well or better than current methods.

You may be eligible if...
- You are 18 or older
- You have melanoma on the head, neck, upper trunk, or limbs; early-stage oral cavity cancer; or penile cancer
- You have no known spread to nearby lymph nodes (clinical N0 stage)
- You are scheduled to have a sentinel lymph node biopsy

You may NOT be eligible if...
- You are allergic to patent blue dye or nanocolloid
- You are pregnant or breastfeeding
- You have had reactions to products containing human albumin
- You have an iodine allergy, overactive thyroid, thyroid nodule, or kidney problems

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

Key Eligibility Criteria

Inclusion (9)

- Patient who will undergo a sentinel node procedure in routine care.
- Patients \> 18 years;
- Patients presenting with:
- a primary cutaneous melanoma of head/neck or upper part of the trunk or extremities;
- OR patients presenting with a primary oral cavity malignancy T1-2N0

... and 4 more (see full listing online)

Exclusion (7)

- Patients with known allergy to patent blue dye or nanocolloid;
- Patients who are pregnant or breast-feeding mothers;
- History of hypersensitivity reactions to products containing human serum albumin;
- History of iodine allergy
- Hyperthyroid or thyroidal adenoma

... and 2 more (see full listing online)

Locations (1 total)

Full details: https://clinicaltrials.gov/study/NCT06666634

NKI-AVL, Amsterdam, Netherlands