Use of SPY Imaging System to Minimize Fistulas After Hypopharyngeal Reconstruction

NCT06831149

Status	RECRUITING
Phase	Phase 2
Sponsor	Matthew Spector
Enrollment	225 participants

Plain Language Summary

This study is testing whether a special imaging system called SPY (which uses a dye and infrared light to check blood supply to tissue during surgery) can help reduce a serious complication called a fistula — an abnormal opening in the throat — after surgery to remove a larynx (voice box) that has been damaged by cancer or radiation.

You may be eligible if...
- You have a confirmed diagnosis of squamous cell carcinoma of the larynx or throat area (stage II–IV)
- You have previously been treated with radiation, with or without chemotherapy
- You have local cancer recurrence, radiation-related tissue damage, or a larynx that no longer functions properly
- You are 18 years or older

You may NOT be eligible if...
- You are allergic to iodine or shellfish
- You cannot safely undergo general anesthesia
- You are pregnant or breastfeeding
- You are currently incarcerated

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

Key Eligibility Criteria

Inclusion (4)

- Prior diagnosis of biopsy-proven squamous cell carcinoma of the larynx or hypopharynx (stage II-IV)
- Prior treatment with radiation +/- chemotherapy
- Presence of local recurrence of disease, radiation necrosis or an incompetent larynx
- years or older. 5. Ability to understand and sign informed consent

Exclusion (5)

- Iodine and Shellfish allergy
- Contraindication to surgery under general anesthesia
- Anticipated extended laryngectomy (laryngopharyngectomy or laryngopharyngoesophagectomy) with the need for free tissue transfer to reconstruct the pharyngeal mucosa. This may only be determined at the time of surgery
- Pregnancy or lactation.
- Patients residing in prison.

Locations (1 total)

UPMC, Pittsburgh, Pennsylvania, United States