

# Clinical Outcomes Modeling for Laryngectomy Surgery Patients and Efficacy of Hyperbaric Oxygen Therapy

**Study Type:** Interventional

**Study Design:** Treatment, Randomized, Open Label, Active Control, Parallel Assignment, Efficacy Study

## **Further Study Details:**

Clinical Outcomes Modeling for Laryngectomy Surgery Patients and Efficacy of Hyperbaric Oxygen Therapy, with Ara Chalian, MD as Project Leader, will develop a predictive model for surgical risk among patients requiring laryngectomy due to cancer, validate the model and assess the efficacy of HB02 therapy for improving outcome. The focus will be to determine the patho-physiological basis for heightened surgical risk among post-radiation head and neck patients and the efficacy of hyperbaric oxygen (HB02) therapy for improving outcome.

This multidisciplinary center will investigate the mechanisms of action, safety, and clinical efficacy of Hyperbaric Oxygen (HB02) Therapy. The group will evaluate if HB02 therapy will benefit patients who must undergo laryngectomy and reconstructive surgery after radiation therapy because, at pharmacological doses, oxygen augments angiogenesis and impedes specific types of intercellular adherence.

The project tests two hypotheses: (1) Predictive models can be developed for sub-groups of head and neck cancer patients who have undergone surgery based on tumor specific site, previous treatment, and co-morbidity and predict which patients will have complications (wound infection and fistula), and (2) HB02 given by a standard protocol can modify tissue hypoxia and vascularity that is present in patients with previous radiation therapy to the neck who have recurrent or secondary cancers requiring laryngectomy. The specific aims are to: (1) develop a detailed database model to predict the risk of developing post-operative complications in complex head and neck aerodigestive tract cancer resections, (2) conduct prospective validation of the predictive model using data on patients treated at the University of Pennsylvania Head and Neck Cancer Center, (3) determine whether hyperbaric oxygen therapy alters post-surgical complication rates and acute and long-term quality of life. The studies include evaluation of clinical parameters, surgical outcome and quality of life measurements, and objective, laboratory-based assessments of the magnitude of hypoxia/vascularization in surgical zones and tumors to provide objective data on surgical risk and clinical responses to HB02 therapy.

## **Eligibility**

### **Ages Eligible for Study:**

18 Years and above , Genders Eligible for Study: Both Criteria The prospective trial allows for planned follow-up and data collection for modeling and tumor oxygenation assessments for patients undergoing laryngectomy. The randomized trial is a treatment trial, comparing standard care before and after laryngectomy to the intervention of pre- & post-operative HBO2 in conjunction with laryngectomy. All patients receive nutritional counseling, speech therapy, and comprehensive peri-surgical care. Patients considering the prospective trial should have : (1) a lesion either suspicious for or diagnosed by biopsy as laryngeal/adjacent pharyngeal cancer requiring a total of partial laryngectomy, (2) no history of radiation to the head/neck,(3)adequate liver and kidney function, and(4) no plans to become pregnant or conceive for the duration of the study. Patients considering the randomized trial should: (1) have been previously irradiated for a head/neck cancer, (2) demonstrate a lesion either suspicious for or diagnosed by biopsy as laryngeal/adjacent pharyngeal cancer, (3)have adequate liver and kidney function, (4) meet physical requirements for hyperbaric oxygen therapy, (5) agree to randomization of care to receive a laryngectomy and standard follow-up care vs. hyperbaric oxygen therapy preoperatively and postoperatively. Expected Total Enrollment: 150

## **Location and Contact Information**

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### **Pennsylvania**

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Study chairs or principal investigators

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