Aortic Laryngeal Rehabilitation Graft

NCT04650919

Status	RECRUITING
Phase	Not Applicable
Sponsor	University Hospital, Strasbourg, France
Enrollment	4 participants

Plain Language Summary

This French surgical trial tests a new type of laryngeal (voice box) replacement using a specially treated aortic graft in patients who need to have their voice box removed due to cancer of the upper airways.

You may be eligible if...
- You have a cancer of the upper airways that requires total removal of the voice box (total laryngectomy)
- You are covered under a French social health insurance scheme
- You can read and understand French and can provide informed consent
- You have a negative pregnancy test (if you are a woman of childbearing age)

You may NOT be eligible if...
- You have a contraindication to general anesthesia or contrast dyes
- You are breastfeeding
- Your cancer extends more than 1 cm below the voice box or to the base of the tongue
- You have previously had radiation to the head and neck area
- You have severe blood clotting disorders
- You have an allergy to certain preservation agents used in the graft procedure

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

Key Eligibility Criteria

Inclusion (5)

- Patient with carcinomatous pathology of the upper airways requiring total laryngectomy
- Patient affiliated to a social health insurance scheme (beneficiary or beneficiary's successor)
- Patient speaks and reads French, understands the objectives and risks of the research and is able to provide dated and signed informed consent.
- Patient having been informed of the results of the prior medical examination
- For a woman with the ability to procreate: negative blood pregnancy test (verified during preoperative blood work) and effective contraception throughout the study.

Exclusion (13)

- Patient with a contraindication to general anaesthesia and/or iodinated contrast agents
- Breastfeeding woman
- Patient with a WHO performance index of grade strictly greater than 2 at the inclusion visit
- Patient with subglottic or basi-lingual tumour extension greater than 1 cm (by endoscopic control and CT scan)
- Patient having undergone cervico-facial radiotherapy prior to surgical management

... and 8 more (see full listing online)

Locations (1 total)

https://clinicaltrials.gov/study/NCT04650919

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