An early clinical feasibility study of a new prosthesis: the NewBreez® Intralaryngeal device; a possible solution for severe aspiration in head and neck cancer patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON42228

Source
ToetsingOnline

Brief title
An intralaryngeal device for a dysfunctional larynx

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
aspiration, Dysfunctional larynx, swallowing impairment

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Antoni van Leeuwenhoek (waarbij ProTiP Medical zorg draagt voor levering van de prothesen),PROTiP Medical

Intervention

Keyword: Aspiration, Dysfunctional larynx, Head and neck cancer, Intralaryngeal prosthesis

Outcome measures

Primary outcome

Safety endpoints:

o Adverse events, including adverse device effects: dislocation, damage to the

larynx

o Implant tolerance

o Reversibility if/when removed

Secondary outcome

Performance and efficacy endpoints:

o Technical success of the implantation procedure

o Implant placement and integrity, as assessed by nasopharyngoscopy

o Eating (diet, oral intake and/or feeding tube dependency)

o Breathing (tracheotomy dependency)

o Aspiration, as assessed by direct visualization and videofluoroscopy at one

week and 6 months after placement

Patient satisfaction:

o Quality of Life, as assessed by the SWAL-QOL questionnaire

o Specific questions on tolerance and problems with the device

Study description

Background summary

Head and neck cancer (HNC) treatment may lead to early and late side effects and complications which affect organ function. Since the larynx plays a central role in the mechanism of swallowing, respiration and voice production, swallowing/respiratory problems are not uncommon following HNC treatment, which may eventually lead to the need for a feeding tube (to ensure proper intake) and/or a tracheotomy (to ensure an open respiratory tract and prevent pulmonary infections). Sometimes a total laryngectomy (TLE) is the only resolution for controlling severely disabling and potentially life-threatening aspiration problems in patients with a dysfunctional larynx1. In order to ensure safe oral intake without the need of a feeding tube, tracheotomy and/or a TLE, several removable intralaryngeal devices has been developed to prevent aspiration of food into the airway, while ensuring normal respiratory function. The NewBreez® intralaryngeal prosthesis is a silicon device with a valve mechanism designed to enable passage of air through a dysfunctional larynx while preventing aspiration through the valve. It is designed to restore normal oral feeding. The aim of this study is to trial this prosthesis in HNC patients with severe respiratory and swallowing disorders related to a dysfunctional larynx, and to investigate whether this device can be placed safely without complications an can obviate the need for total laryngectomy.

Study objective

This is a feasibility study to assess this new device after 6 months use.

There are 3 objectives that have to be fulfilled in order use this device in the future:
1. Safety of the NewBreez® at 6 months: has there been further damage done to the larynx?
2. Performance and efficacy of the NewBreez® at 6 months: is the device functioning and preventing aspiration and not causing any airway complications. Would decanulation of the trachea cannula and removal of the PRG tube be an option?
3. Patient satisfaction: is the patient satisfied and does he/she have improved quality of life?

Study design

Non-randomized, open-label, prospective clinical feasibility study

Intervention

Placement of the NewBreez® Intralaryngeal prosthesis.

Study burden and risks

The general benefits of using the NewBreez® Intralaryngeal device include the possibility to restore natural breathing and to allow natural feeding. As there is a risk of obstruction with mucous and crusts, we will only include patients with a tracheostomy to prevent this complication. There is a risk that there is still aspiration when the food does not pass quickly through the upper esophageal sphincter or in case of a dysfunctioning valve. A serious side effect is that the patient will probably become aphonic and has a whispery voice.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patients who have been treated successfully for HNC and are free of disease minimally one year after treatment; and
- Patients with difficulties in feeding and/or breathing due to a dysfunctional larynx, necessitating prolonged (> 6 months) use of a (nasogastric or percutaneous) feeding tube and a tracheotomy, which are unlikely to be removed; and
- Patients who are motivated to undergo the operation; and
- Patients are willing to provide written informed consent prior to participation.

Exclusion criteria

- Patients under the age of 18 years; or
- Patients with clotting disorders; or
- Patients with Chronic Obstructive Pulmonary Disease (COPD); or
- Patients with recurrent or residual HNC disease; or
- Patients with upper esophageal obstruction or stenosis on videofluoroscopy; or
- Patients who are unfit to undergo general anaesthesia, as judged by the anaesthetist.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2014
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	NewBreez® Intralaryngeal Prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-08-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL51129.031.14