Feasibility study of a mouldable peristomal adhesive for pulmonary and speech rehabilitation after total laryngectomy.

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The novel mouldable peristomal adhesive (Provox Life FreeHands Adhesive) can be modelled to the patient*s neck and stoma shape when warmed, and remains its shape when cooled. The hypothesis is that this mouldable peristomal adhesive will improve the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON48404

Source
ToetsingOnline

Brief title
Mouldable peristomal adhesive for rehabilitation after total laryngectomy

Condition

- Head and neck therapeutic procedures

Synonym
laryngectomy, removal of larynx

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: NKI-AvL

Intervention

Keyword: heat and moisture exchanger, laryngectomie, mouldable adhesive, stoma

Outcome measures

Primary outcome

The primary objective of this study is to investigate the product performance of Provox Life FreeHands Adhesive in combination with hands-free speech, in subjects with a total laryngectomy, with the use of a study specific structured questionnaire. Product performance is defined as the individual fit, experienced comfort, user-friendliness, usability, and reasons for non-compliant use (device or non-device related).

Secondary outcome

The secondary objective is to evaluate the device lifetime during hands-free speech and duration of hands-free speech compared to their standard peristomal adhesive (difference in [hours] or [hours/day], per subject) and the self-assessed subject satisfaction of Provox Life FreeHands Adhesive with the use of two study specific structured questionnaire.

Study description

Background summary

One of the consequences of a total laryngectomy (TL) is a complete disconnection of the upper and lower airways. After TL, the patient is breathing through a permanent tracheostoma in the neck. To aid pulmonary rehabilitation, patients use a heat-moisture exchanger (HME). The HME can be fixated in front of the tracheostoma opening with either a peristomal adhesive or intratracheal tube or button. An automatic speaking valve (ASV) in

combination with an HME allows hands-free speech and removes the need to occlude the stoma with the finger. Hands-free speech does exercise more stress on the fixation product, which can lead to the loosening of the fixation product or leakage of air. The novel mouldable peristomal adhesive (Provox Life FreeHands Adhesive) can be modelled to the patient*s neck and stoma shape when warmed, and remains its shape when cooled. The hypothesis is that this mouldable peristomal adhesive will improve the individual fit and duration of fixation during hands-free speech, which can result in a better overall product performance during hands-free speech and self-assessed subject satisfaction (preference and acceptance) compared to the standard peristomal adhesive

Study objective

The novel mouldable peristomal adhesive (Provox Life FreeHands Adhesive) can be modelled to the patient*s neck and stoma shape when warmed, and remains its shape when cooled. The hypothesis is that this mouldable peristomal adhesive will improve the individual fit and duration of fixation during hands-free speech, which can result in a better overall product performance during hands-free speech and self-assessed subject satisfaction (preference and acceptance) compared to the standard peristomal adhesive

Study design

prospective monocentre feasibility study

Intervention

All subjects are asked to use the mouldable peristomal adhesive (Provox Life FreeHands Adhesive) for two consecutive weeks in combination with their normal routine for application and removal of the adhesives and HME, and speech rehabilitation.

Study burden and risks

No new risks have been identified related to the use of Provox Life Freehands Adhesive.

A one-time visit is required at the start of the study to collect the baseline data and to provide the study materials. This visit will take approximately 45 minutes

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Total laryngectomized patient
- 18 years or older
- Voice prosthesis users
- Regular hands-free speech users: ASV with integrated HME
- Peristomal adhesive users (StabiliBase, XtraBase, FlexiDerm)
- Longer than 3 months after total laryngectomy
- Longer than 6 weeks after postoperative radiotherapy

Exclusion criteria

- LaryTube or LaryButton users
- Medical problems prohibiting the use of HME, ASV and/or adhesives
- Active recurrent or metastatic disease
- Reduced mobility of arms and/or hands
- Unable to understand patient information and/or to give informed consent

- Insufficient cognitive ability to handle the HME, ASV or mouldable adhesive

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Provox Life FreeHands Adhesive
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-11-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	09-09-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL70725.031.19