Clinical assessment of a new speaking valve for hands-free speech in laryngectomized patients: Provox® FreeHands FlexiVoice

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The objective of this clinical investigation is to evaluate the short- and long-term clinical feasibility of the Provox FreeHands FlexiVoice, in combination with the currently available attachments, and explore its limitations and advantages.

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

Summary

ID

NL-OMON40854

Source
ToetsingOnline

Brief title
Clinical assessment of a new hands-free speaking valve

Condition

- Head and neck therapeutic procedures

Synonym
Laryngectomy, removal of larynx

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek

Source(s) of monetary or material Support: Atos Medical AB,Atos Medical AB and Hospital (collaboration)

Intervention

Keyword: handsfree speech, Heat and Moisture Exchanger, laryngectomy

Outcome measures

Primary outcome

As this study is a clinical feasibility study, there are no specific outcomes

for this study.

Secondary outcome

As this study is a clinical feasibility study, there are no specific outcomes

for this study.

Study description

Background summary

Since the first handsfree speaking valves for laryngectomees were introduced to the market in the early eighties, several devices with incremental changes have been developed. The Provox FreeHands HME that was introduced in 2003 was the first handsfree speaking valve with an integrated HME for pulmonary rehabilitation. The main drawback of all handsfree speaking valves is that it can be problematic to get a good seal of the adhesive to withstand the pressure generated during speaking. In this study a newly developed handsfree speaking valve will be tested. The new speaking valve can be used for hands free speech and can also be occluded manually. The speaking valve has been developed with the aim to increase the proportion of subjects able to successfully use a handsfree speaking valve.

Study objective

The objective of this clinical investigation is to evaluate the short- and long-term clinical feasibility of the Provox FreeHands FlexiVoice, in combination with the currently available attachments, and explore its limitations and advantages.

Study design

This study will be a non-randomized prospective multi-center study in 40 laryngectomized subjects. Clinical feasibility of the Provox Freehands FlexiVoice will be investigated with a focus on both short- and long-term performance and compliance. The outcomes will be recorded by means of structured and comparative questionnaires, voice assessment, VAS scales, EQ-5D, and subject diaries.

Intervention

Subjects will first use the Provox FreeHands FlexiVoice for a period of two weeks in order to get used to the device. After that, the patient will be phoned for follow-up and will be offered support from either the speech pathologist or the investigator, if needed. Then, the subject will visit the hospital after one month for voice assessment and questionnaires. A short follow-up is done per phone at month 2, 3, 4 and 5. At month 6, the end of the study, the subject can either come back to the hospital or complete the final questionnaires by phone.

Study burden and risks

No new risks have been identified related to the Provox FreeHands FlexiVoice. It is expected that the study may be of some burden to some subjects due to the fact that the subjects are required to keep a diary of their experiences with the attachment methods and the use of the Provox FreeHands FlexiVoice. And it could also be a burden for them if the automatic speaking valve that they are asked to try out does not work well for them. Also the visits to the hospital can be experienced as burdensome. Visit 1 and 2 are expected to take 45 minutes. The last visit/phone call will likely be shorter in duration. The follow-ups by phone will all be short.

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 laryngectomy
18 years or older
HME user and/or handsfree speaking valve user
Voice prosthesis user
Longer than 3 months after total laryngectomy or postop radiotherapy

Exclusion criteria

Patient is unable to remove or operate the device
Active recurrent or metastatic disease (medical deterioration)
Unable to complete patient diaries
Unable to understand the Patient Information and/or unable to give Informed Consent

Study design

Design

Study phase:	4
Study type:	Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-01-2014
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Provox FreeHands FlexiVoice
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-04-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL48328.031.14