Early clinical feasibility study of a new voice prosthesis: the Provox Vega HP

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

Summary

ID

NL-OMON38672

Source
ToetsingOnline

Brief title
Provox Vega HP study

Condition

- Head and neck therapeutic procedures

Synonym
'total laryngectomy' 'voice rehabilitation'

Research involving
Human

Sponsors and support

Primary sponsor: Atos Medical AB
Source(s) of monetary or material Support: Atos Medical

Intervention

Keyword: total laryngectomy, voice prosthesis, voice rehabilitation

Outcome measures

Primary outcome

The design of the study is in line with the early nature of the investigation and is observational. There are no specific outcome measures or endpoints. The investigation will cover the advantages and limitations of the new valve flap design and material related to short-term aspects such as noise of VP, bloating issues, leakage, inadvertent opening of the valve (i.e. leakage), and stickiness of the valve, voice and speech quality, speaking effort, and possible effects on voice prosthesis cleaning procedures, frequency and effectiveness of cleaning.

Secondary outcome

Not applicable

Study description

Background summary

Since voice prostheses were introduced on the market in the eighties, several changes of the devices have taken place. Some of the incremental changes were to further improve the device, but new types of devices were also developed for specific populations, such as the Provox ActiValve. In this study, a newly developed voice prosthesis will be tested: the Provox Vega HP. The prosthesis has been developed with the aim of increasing device life. Before conducting a long-term study investigating device life, the limitations and advantages of the Provox Vega HP need to be explored in this early clinical feasibility study.

Study objective

The objective of this clinical investigation is to evaluate the short-term clinical feasibility of Vega HP and explore its limitations and advantages. As a result of the evaluations, design changes may be implemented and evaluated until the optimal design has been determined, or until it is decided not to pursue further development of the device.

Study design

Prospective Phase I feasibility study in which 8 current Provox Vega users and 8 current Provox ActiValve Light users will be recruited for the study.
Patients will use the Provox Vega HP for two weeks to investigate short term feasibility and explore limitations and advantages. If the patient does not experience any problems and wishes to leave the Provox Vega HP in situ, this will be allowed under the condition that the subject agrees to remain in the study and report adverse events on an ongoing basis, until the device is removed after a maximum of 6 months.

Intervention

Use of the Provox Vega HP for the duration of two weeks with the option of leaving the device in situ until replaced for device failure or other reason, with a maximum of 6 months.

Study burden and risks

Since all subjects are current voice prosthesis users, no additional or other risks are expected when using the Provox Vega HP instead of the Provox Vega or Provox ActiValve Light.
The patient may consider the replacement of the prosthesis as a burden. However, patients require regular replacements and are therefore accustomed to the procedure. Depending on the performance of the new Provox Vega HP, it is possible that the Provox Vega users may experience stickiness of the valve flap leading to blockage and higher speaking effort as a burden, and that Provox ActiValve users may experience inadvertent valve opening during swallowing and/or inhalation possibly leading to intermittent leakage or gastric filling/bloating as a burden. Also the outpatient clinic visits and completion of the questionnaires at baseline and after two weeks, and the follow-up by phone during long term use of the Vega HP may be considered a burden.

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

Laryngectomized patients using either the Provox Vega or the Provox ActiValve Light voice prosthesis, with a length of 6, 8, or 10 mm
Age: 18 years or older

Exclusion criteria

-Current tracheoesophageal puncture problems such as enlarged puncture or infection
-Active recurrent or metastatic disease (medical deterioration)
-Unable to understand the patient information and/or unable to give informed consent

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):	18-10-2013
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	Voice Prosthesis; Provox Vega HP
Registration:	No

Ethics review

Approved WMO

Date:	25-09-2013
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	NL45171.031.13