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	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON50825

Source
ToetsingOnline

Brief title
Vega HP study

Condition

- Other condition

Synonym
Larynx extirpation, removal of the larynx

Health condition

Patienten na laryngectomie met stemprothese

Research involving
Human

Sponsors and support

Primary sponsor: Atos Medical AB
Source(s) of monetary or material Support: Unrestricted research grant Atos Medical aan Afd hoofhals oncologie en chirurgie AVL

Intervention

Keyword: Feasibility, Total laryngectomy, Voice prosthesis

Outcome measures

Primary outcome

The research concerns the advantages and limitations of the new valve design

and material with respect to short term aspects such as valve stickiness, voice

quality and difficulty speaking.

Secondary outcome

Stickiness of the valve, speaking effort, voice quality.

Study description

Background summary

Feasibility of the novel voice prosthesis Provox Vega HP.

Study objective

The objectiveof this study is to evaluate the short term clinical applicability of the Provox Vega HP and to investigate its potential limitations and benefits. As a result of the evaluations, the design could be adapted to arrive at the optimal design. The main result is the acceptance of the Provox Vega HP and the patient's preference. Secondary outcomes are stickiness of the voice prosthesis and speech.

Study design

This is a prospective feasibility study in which 15-20 patients will be recruited. Patients will use the Provox Vega HP for two weeks to evaluate short-term feasibility and explore limitations and benefits. Voice recordings

are made twice, with the current voice prosthesis and with the Provox Vega HP. Participants complete questionnaires twice; Before the study and after wearing the Provox Vega HP for 2 weeks.
If the participant wishes to leave the Provox Vega HP in situ after the 2 study weeks, this is allowed on the condition that the subject agrees to remain in the study and to report (adverse) events continuously, until the voice prosthesis is removed after a maximum of 12 months.

Study burden and risks

There are no risks associated with the research. The voice prosthesis change can be experienced as a burden. Daily care of the voice prosthesis with lubricant can be experienced as a burden.

Contacts

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SE
Scientific
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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 22.5 or the Provox ActiValve Light voice prosthesis, with a length of 4, 6, 8, or 10 mm
• 18 years and older

Exclusion criteria

• Current tracheoesophageal puncture problems such as enlarged puncture or infection
• Active recurrent or metastatic disease (medical deterioration)
• The use of ActiValve Strong/XtraStrong or XtraSeal
• Unable to understand the Patient Information and/or unable to give Informed Consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2022
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Provox voice prosthesis Vega HP
Registration:	No

Ethics review

Approved WMO Date:	17-12-2021
Application type:	First submission
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	NL76694.031.21