Clinical Feasibility of a new adhesive base plate (placeholder for stoma appliances) for rehabilitation after total laryngectomy

Published: 15-04-2010
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To investigate the clinical feasibility of the Provox StabiliBase adhesive.

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

Summary

ID

NL-OMON34698

Source
ToetsingOnline

Brief title
Feasibility of new tracheostoma baseplate

Condition

- Head and neck therapeutic procedures

Synonym
laryngectomy, removal of larynx

Research involving
Human

Sponsors and support

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

Intervention

Keyword: HME, laryngectomy, tracheostoma

Outcome measures

Primary outcome

Patient preference

Secondary outcome

Device life of the adhesive

Patient satisfaction

Voice and Speech (perceptual evaluation, maximum phonation time, phrasing)

Ease of application

Study description

Background summary

One of the consequences of a total laryngectomy is a complete disconnection of the upper and lower airways. After this type of surgery, the patient is breathing through a permanent tracheostoma in the neck. Several appliances (Heat and Moisture Exchangers (HMEs) to condition the inhaled air, handsfree speaking valves to allow speaking without the need to occlude the stoma with a finger, and shower aids to prevent water from entering the airways while showering) are used in front of the tracheostoma. These appliances are held in front of the stoma by means of adhesive base plates, laryngectomy tubes, or tracheostoma buttons. Although a variety of adhesives exists, further improvement is possible and desired.
The new Provox StabiliBase is has a more stable base than the current range of adhesives, combined with a FlexiDerm plaster. The adhesive is expected to be a better solution than the current adhesives for a proportion of the patients. In those patients it is expected to last longer, fit better and perhaps lead to better voice and speech and longer use of a handsfree speaking valve.
A user study is necessary to assess the clinical feasibility of this new adhesive.

Study objective

To investigate the clinical feasibility of the Provox StabiliBase adhesive.

Study design

The study will be a non-randomized prospective controlled study in which the patients will serve as their own controls. The study will consist of three parts. All patients will participate in part 1 and 2, only patients wishing to continue and (previously) using a handsfree speaking valve will participate in part 3. The study is not randomized because that would eliminate the possibility to collect useful baseline data.

Intervention

Application of an adhesive base plate to the peristomal skin.

Study burden and risks

No new risks have been identified related to this new adhesive.
It is expected that the study may be of some burden to some patients due to the 3 required visits in 5 weeks time and the request to keep a patient diary. The patient information and informed consent procedure will take about 10 minutes. Each visit is expected to take 45 minutes.

Contacts

Public
Atos Medical

Kraftgatan 8
24222
Zweden
Scientific
Atos Medical

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24222
Zweden

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

laryngectomy
voice prosthesis user
HME user

Exclusion criteria

skin problems tracheostoma, allergy to adhesive
medical problems prohibiting HME use

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2010
Enrollment:	50

Type:	Actual

Medical products/devices used

Generic name:	Provox StabiliBase Adhesive
Registration:	No

Ethics review

Approved WMO Date:	15-04-2010
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	NL31745.031.10