Clinical assessment of a new adhesive and HME for night-time use in laryngectomized patients: Provox Luna

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The objective of this clinical investigation is to evaluate the clinical performance of Provox Luna in comparison to the usual care of the patient.

Ethical review	Not approved
Status	Will not start
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON43035

Source
ToetsingOnline

Brief title
Clinical assessment of the Provox Luna

Condition

- Head and neck therapeutic procedures

Synonym
Laryngectomy, removal of larynx

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Adhesive, Heat and Moisture Exchanger, Laryngectomy, Stoma

Outcome measures

Primary outcome

The primary outcome measure is compliant use of the HME.

Secondary outcome

The secondary outcome measures for the Provox Luna Adhesive are performance (stickiness, comfort, cooling and soothing of the skin, visibility of the skin) and skin effects (healing/recovering of skin, severity and frequency of skin irritation and pain reduction). The secondary outcome measures of the Provox Luna HME are performance (breathing, speaking, comfort of the device), pulmonary effects (coughing, forced expectorations, tracheal irritation, mucus production) and Quality of Life (sleeping, EQ-5D).
Overall satisfaction with Provox Luna (both the adhesive and the HME) is also a secondary outcome measure.

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. Laryngectomized patients use a variety of devices in front of the tracheostoma: Heat and Moisture Exchangers (HMEs) to condition the inhaled air, hands free 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. A variety of attachment methods is available, such as adhesives in different types, designs and shapes. However, feedback from clinicians and patients has revealed that some patients experience skin irritation when using certain

adhesives. In literature skin irritation is reported on average in about 20% of the laryngectomized patients, with a range from 9% to 40%1-7. A large survey (n=729) performed by Atos Medical (2015) showed that 47% of the patients sometimes experience skin irritation and lets the skin rest by not using an adhesive for a period of time. This number is higher than the 20% reported in the literature. However, skin irritation was not usually an outcome measure in these studies, but mostly reported as a negative effect (adverse effect) of the adhesives used in the studies. In the survey patients were specifically asked questions concerning skin irritation. This could explain the difference in reported percentage between literature and the survey, where we believe the 47% of the survey is probably more representative than the average percentage of 20% mentioned in literature.

The survey shows that on average the patients let their skin rest 2.2 days per week, and mostly during the night. During skin rest the patients do not use any adhesives, and consequently the assumption is that they do not use an HME. The high percentage in this survey shows the importance of an adhesive that has the potential to decrease skin irritation and therefore to potentially increase compliant use of HMEs. Furthermore, feedback from patients revealed that wearing an adhesive with HME during night-time is sometimes considered uncomfortable. Instead, patients use alternatives, such as bibs and scarves, or nothing at all. Therefore, compliant HME use (24/7) is not achieved by all patients, which has a negative effect on pulmonary rehabilitation. Hence, a new default solution for night-time use is developed, Provox Luna.

Provox Luna consists of an adhesive and an HME. Provox Luna Adhesive is a new adhesive, made of a hydrogel material. Hydrogels are commonly used on a wide variety of wounds, such as skin tears, pressure ulcers, burn wounds and surgical wounds. Hydrogel dressings are water- or glycerin-based products, best suited for dry wounds or those with minimal to moderate exudates8, 9. Hydrogel sheet dressings are reported to be comfortable and soothing, and to reduce pain because of their cooling effect10-14. Although the use of hydrogel has been widely described in the medical literature, hydrogel adhesives have so far not been used for the stoma area of laryngectomized patients.

Provox Luna HME is a soft silicone HME with a pressure drop of 55Pa at 30L/min and a moisture loss of 21.4mgH_2O/L air. With these values, the humidification properties of the Provox Luna HME are the same as for the Provox XtraMoist, whereas the pressure drop and hence the breathing resistance, is lower than for the Provox XtraMoist (with a pressure drop of 70Pa) and slightly higher than that of the Provox XtraFlow (with a pressure drop of 40Pa). These properties are intended to enhance comfort during sleep. Silicone is widely used in products for laryngectomized patients, but has so far not been used as material for HMEs.

The current available adhesives and HMEs are focused primarily on daytime use

and speaking. Provox Luna is intended as a night time solution for laryngectomized patients and is expected to reduce or avoid skin irritation and increase comfort. This is expected to lead to increased compliant HME use, thereby optimizing pulmonary rehabilitation.

Study objective

The objective of this clinical investigation is to evaluate the clinical performance of Provox Luna in comparison to the usual care of the patient.

Study design

A multi-center time-series observational study with multiple measurements in which the patients will act as their own control. The study will consist of two periods of four weeks with multiple data collection points.

This study design is chosen in order to reduce bias. Use of the new Provox Luna is expected to influence the behavior of the patient and thereby their answers regarding usual care. The first period of 4 weeks with double baseline and daily diary will give reliable and valid data concerning the usual behavior and use of products, making it possible to compare their usual behavior to the period when they use the Provox Luna in addition to their usual products.

Intervention

The study will consist of two periods of four weeks with multiple data collection points. In the first period of four weeks, patients will document their usual use of attachments and HMEs. After these four weeks, the patients will receive Provox Luna. In the second period of four weeks patients will be asked to use Provox Luna as often as needed or wanted, but with a minimum of 8 nights, supplementary to their usual products. Data collection will take place at zero and four weeks in the first period, and at four weeks in the second period.

Study burden and risks

No risks have been identified related to Provox® Luna when used as intended. It is expected that the study may be of some burden to some patients due to the fact that the participants are required to keep a diary of their experiences with Provox Luna and their usual care. However, the diaries have been kept as short as possible. It could also be a burden for them if the products they are asked to try out do not work well for them. Also the visits to the hospital can be experienced as burdensome. Visits are required at the beginning of the study to collect baseline data, after a month to collect usual care data and to receive the devices, and after two months to collect Provox Luna data. These

visits will take about 45 minutes. 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
Longer than 3 months after total laryngectomy or postop radiotherapy

Exclusion criteria

Medical problems prohibiting the use of HME or adhesive
Active recurrent or metastatic disease (medical deterioration)
Reduced mobility of arms and/or hands, unable to remove an HME
Unable to understand the Patient Information and/or unable to give Informed Consent
Insufficient cognitive ability to handle the HME or adhesive
Use of LaryTube during night on medical prescription (e.g. shrinking stoma)
Too low tidal volume as this may cause carbon dioxide retention

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	45
Type:	Anticipated

Medical products/devices used

Generic name:	Provox Luna
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	10-08-2016
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	NL57804.031.16