Inhalation Valve

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The overall aim of the study is to evaluate the difference in speech performance of a new hands-free speech valve as compared to the currently most used (Atos) exhalation speech valve.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33932

Source
ToetsingOnline

Brief title
Inhalation Valve

Condition

- Other condition

Synonym
tracheostoma

Health condition

medisch hulpmiddel voor mensen na laryngectomie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hands-Free, Inhalation, Speech, Tracheostoma valve

Outcome measures

Primary outcome

The difference in speech power (maximum phonation time multiplied with the maximum loudness) of both types of speechvalves.

Secondary outcome

The difference in maximum amount of words using one breathe while reading a standardised text.

Study description

Background summary

A number of the patients with laryngeal cancer have to be treated with a total laryngectomy. As part of the rehabilitation, a shunt valve can be placed in a tracheostoma between the trachea and the oesophagus. If the patient wants to speak, the stoma is closed with a finger or thumb to force expired air through the shunt valve into the oesophagus. Soft tissue at the top of the oesophagus starts to vibrate and functions as new vocal folds.
Some of these patients use a tracheostoma valve (TV) on their stoma. This enables them to speak without using their hands.
The department of biomedical engineering of the faculty of medicine at the University of Groningen, has developed a new TV. This new TV is automatically closed by inhalation, in contrast to the currently used exhalation valves (Atos). By this means the patient should be able to save more air for phonation. Expectations 1) patients are able to speak longer using the new TV. 2) patients can speak louder using the TV.

Study objective

The overall aim of the study is to evaluate the difference in speech performance of a new hands-free speech valve as compared to the currently most used (Atos) exhalation speech valve.

Study design

The pilot study is a RCT with a crossover design.

Intervention

New developed hands free Inhalation Valve made by the Department of BioMedical Engineering (BME) of the University Medical Center Groningen, The Netherlands.

Study burden and risks

About 60 minutes of their time is required in addition to them already being present for their routine check-up or appointment. The burden on the patient is minimal. The tests are non-invasive and there are no extra risk factors expected in participating in the study. No patients have ever tried the IV and it is possible that they can benefit from the use of the IV. A better tracheostoma valve can mean a more comfortable voice production.

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

Post-laryngectomees aged between 45 and 70 that have been using a TE shunt prosthesis for their phonation for at least six months.

Exclusion criteria

Excluded are patients with ulceration, infection or metastasis around or in the stoma or severe respiratory problems. Generally excluded are patients in such bad health that cooperation with this study is too heavy a burden.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2009
Enrollment:	14
Type:	Actual

Medical products/devices used

Generic name:	Tracheostoma valve
Registration:	No

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL23245.042.09