# Multicenter randomized 2x2 cross-over study for patient satisfaction and function of the ProTrach DualCare

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In this research we want to determine whether patients prefer the ProTrach DualCare over other speaking valves, if it improves quality of life, compliance with HME use and lung function.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Upper respiratory tract disorders (excl infections) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON40675

**Source**
ToetsingOnline

**Brief title**
Multicenter study for patient satisfaction of the ProTrach DualCare

### Condition

- Upper respiratory tract disorders (excl infections)

**Synonym**
airway opening, Tracheotomy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Atos Medical AB and hospital (collaboration),Atos Medical BV

## Intervention

**Keyword:** DualCare, HME, speaking valve, Tracheotomy

## Outcome measures

### Primary outcome

The main parameter tested will be patient preference.

### Secondary outcome

Secondary parameters are quality of life (QOL), lung function, breathing

resistance, swallowing, olfaction, quality of speech and compliance.

# Study description

### Background summary

Tracheotomized patients lack the function of the upper airway: moisturizing, warming and filtering the air. Heat and Moisture Exchangers (HME) are developed to regain some of the upper airway functions: moisturizing, filtering larger particles, and heating the air. An HME works by retaining the heat and moisture of exhaled air passing through it. This is associated with better lung function and less secretions.
Furthermore tracheotomized patients are unable to speak as the air is not passed through the vocal cords. The loss of speech is resolved by patients closing their tracheostomy tube with a finger or by a speaking valve redirecting the air through the upper airway. A speaking valve contains a membrane that is closed when patients exhale. Advantages of a speaking valve are hands free use, reduction of aspiration by maintaining subglottic pressure, better olfaction and less damage of trachea and skin.
Until now one had to choose between a speaking valve and an HME. With the ProTrach DualCare (Atos Medical, Hörby, Sweden) a speaking valve and functional HME are combined in one device, using a *speaking* and an *HME* mode. This is expected to improve lung function, and quality of life (QOL) of tracheotomized patients depending on their original device.

### Study objective

In this research we want to determine whether patients prefer the ProTrach DualCare over other speaking valves, if it improves quality of life, compliance

with HME use and lung function.

### Study design

The study is a multicenter randomized 2x2 cross-over design. Allocation of the patients to the two treatment orders will be randomized within center, but the study is not blinded as the patient and the investigator will know that the ProTrach DualCare is used.

### Intervention

The ProTrach DualCare.

### Study burden and risks

Risks using the ProTrach DualCare include higher breathing resistance in speaking mode, clogging of the ProTrach DualCare HME with coughed up phlegm and increased mucus production in the first days of use due to the HME effect.

## 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

18 years or older;
have a tracheostomy;
sufficient cognitive ability for handling the ProTrach DualCare;
sufficient manual dexterity for handling the ProTrach DualCare;
are capable of using a speaking valve;
adequate upper airway

## Exclusion criteria

use of a tube that does not allow air passage around the tube;
laryngectomized;
mechanically ventilated 24/7;
cannot tolerate added dead space or breathing resistance from study devices;
severe airway obstruction;
severe aspiration;
thick and copious secretions;
unable to understand the Patient Information and/or unable to give Informed Consent;
patient does not have a 15mm or 22mm connector

# Study design

## Design

| | |
|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-01-2015 |
| Enrollment: | 40 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | ProTrach DualCare |
| Registration: | Yes - CE intended use |

## Ethics review

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| Approved WMO Date: | 29-09-2014 |
| 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 | NL49286.042.14 |