# Cost-effectiveness study on the provox®2 and the Groningen ultra low resistance tracheoesophageal shunt prostheses

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/12/2006		<pre>Protocol</pre>		
Registration date 28/12/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
06/01/2021	Ear, Nose and Throat			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr K Harms

#### Contact details

University Medical Center Groningen (UMCG) Deparment of ENT P.O. Box 30001 Groningen Netherlands 9700 RB

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ABR NL12933.042.06, NL777, NTR788

# Study information

#### Scientific Title

Cost-effectiveness study on the provox®2 and the Groningen ultra low resistance tracheoesophageal shunt prostheses

# **Study objectives**

Hypothesis 1: the Groningen Ultra Low Resistance (ULR) and the Provox®2 are the same in terms of the replacement method, the burden on the patient and the convenience of the replacement and of the resistance during phonation.

Hypothesis 2: the Groningen ULR has a longer lifetime than the Provox®2 and is thus less expensive in use.

Hypothesis 3: the quality of life of the patient is higher while using the Groningen ULR than when using the Provox®2.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Ethics approval received from the local medical ethics committee

#### Study design

Prospective randomised, controlled, crossover group trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

Treatment

# Participant information sheet

# Health condition(s) or problem(s) studied

Tracheoesophageal shunt prostheses following laryngectomy

#### **Interventions**

Prospective randomised cross-over design with a group of 80 patients aged 45 to 70 out of our population of over 134 post laryngectomy patients that have been using a TracheoEsophageal Shunt Prostheses (TESP) for their phonation for at least six months. The patients are randomly divided into four groups according to the following schedule:

Group 1, 20 persons: G-G-G Group 2, 20 persons: G-G-P Group 3, 20 persons: P-P-G Group 4, 20 persons: P-P-P

G= Groningen ultra low resistance

P= Provox®2

# Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Lifetime of both types of TE shunt prosthesis

# Secondary outcome measures

- 1. Total costs for the use of both the Provox®2 and Groningen ULR TE shunt prostheses. An incremental cost analysis.
- 2. Quality of life.
- 3. Evaluation of both types of prostheses.
- 4. Preference of patients for one of both types of prostheses.
- 5. Experience with replacement and -technique.
- 6. Diet: Food products that influence lifetime of the TE shunt prosthesis.
- 7. Expenses made by patient.

# Overall study start date

01/11/2006

# Completion date

10/04/2008

# Eligibility

#### Kev inclusion criteria

Patients from our outpatient clinic (Ear, Nose and Throat [ENT] Department at University Medical Centre Groningen [UMCG]): post-laryngectomees that use a TracheoEsophageal (TE) shunt prosthesis for their phonation.

# Participant type(s)

Patient

#### Age group

Adult

#### Sex

**Not Specified** 

# Target number of participants

#### Total final enrolment

80

# Key exclusion criteria

- 1. Patients younger than 45 or older than 70
- 2. Patients that have a metastasis or recurrence of their previous larynx carcinoma
- 3. Patients that smoke tobacco

#### Date of first enrolment

01/11/2006

# Date of final enrolment

10/04/2008

# Locations

#### Countries of recruitment

Netherlands

# Study participating centre University Medical Center Groningen (UMCG)

Groningen Netherlands 9700 RB

# Sponsor information

#### Organisation

University Medical Center Groningen (UMCG) (The Netherlands)

# Sponsor details

c/o Dr. B. van der Laan Head of Department of Ear, Nose and Throat Medicine P.O. Box 30001 Groningen Netherlands 9700 RB

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.rug.nl/umcg/index?lang=en

# ROR

https://ror.org/03cv38k47

# Funder(s)

# Funder type

Not defined

# Funder Name

Not provided at time of registration

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011	06/01/2021	Yes	No