

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Lifetime of both types of TE shunt prosthesis

Key secondary outcome(s))

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.

Completion date

10/04/2008

Eligibility

Key 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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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)

ROR
<https://ror.org/03cv38k47>

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

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