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

Submission date	Recruitment status	[_] Prospectively registered
28/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/12/2006	Completed	[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

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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

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

Age group
Adult

Sex
Not Specified

Target number of participants

80

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