Evaluation of rehabilitation in postlaryngectomy patients

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/02/2008		☐ Protocol		
Registration date 13/03/2008	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
22/08/2011	Cancer			

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

N/A

Study information

Scientific Title

Predictive value of oesophageal computerised manometry after total laryngectomy in patients with voice prosthesis: evaluation of pharyngo-oesophageal segment

Study objectives

There is a cutoff value for determination of patients with and without spasm of pharyngooesophageal segment under computerised manometry exam.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Ethics in Research Committee from State University of Campinas on the 6th May 2007 (ref: 036/2007 description CAAE: 0020.0.146.000-7).

Study design

Criterion standard: a study of screening and diagnostic tests

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Cancer of larynx, voice disorders

Interventions

Follow-up ranged from two to seven years:

- 1. One group with 12 patients were without spasm, confirmed by videofluoroscopy as "gold standard" of pharyngo-oesophageal segment and the tests perceptive voice analysis, videofluoroscopy and computerised manometry were performed
- 2. One group with 8 patients had spasm of pharyngo-oesophageal segment confirmed by videofluoroscopy as "gold standard", performed perceptive voice analysis, videofluoroscopy and computerised manometry, too. After they were treated with 100 units of botulinum toxin injection in the pharyngo-oesophageal segment and after one month perceptive voice analysis, videofluoroscopy and computerised manometry were repeated.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Evaluation of a cutoff value for diagnosis of spasm of pharyngo-oesophageal segment (PES) with computerised manometry (CM) or PES in total laryngectomy (TL) patients.

In the group without spasms, outcomes were measured after selection criteria were established. In the group with spasms, after the requirements of selection criteria were fulfilled, the patients were selected and all measurements were done. Then treatment with botulinum toxin was done and after one month of application of toxin all measurements were repeated.

Key secondary outcome(s))

- 1. Evaluation of degree of statistical difference of mean values of computerised manometry between patients with and without spasm
- 2. Evaluation of improvement of fluency of speech in patients with spasm after application of botulinum toxin in pharyngo-oesophageal segment

In the group without spasms, outcomes were measured after selection criteria were established. In the group with spasms, after the requirements of selection criteria were fulfilled, the patients were selected and all measurements were done. Then treatment with botulinum toxin was done and after one month of application of toxin all measurements were repeated.

Completion date

15/09/2005

Eligibility

Key inclusion criteria

- 1. Submitted to total laryngectomy
- 2. Rehabilitated with voice prosthesis
- 3. With tracheoesophageal voice
- 4. With and without spasm
- 5. Diagnosed with videofluoroscopy under phonation and deglutition
- 6. Adults of either sex

All patients submitted to perceptive voice analysis, videofluoroscopy under phonation and deglutition and computerised manometry. Patients treated with botulinum toxin injection in pharyngo-oesophageal segment were submitted to all examinations before and after treatment.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Not submitted to total laryngectomy
- 2. Without voice prosthesis
- 3. Without any of the exams:
- 3.1. Perceptive voice analysis
- 3.2. Videofluoroscopy under phonation
- 3.3. Deglutition
- 3.4. Computerised manometry
- 4. Those submitted to treatment of spasm, when any of these exams were not performed before and after treatment:
- 4.1. Perceptive voice analysis
- 4.2. Videofluoroscopy under phonation

4.3. Deglutition

4.4. Computerised manometry

Date of first enrolment

10/03/2000

Date of final enrolment

15/09/2005

Locations

Countries of recruitment

Brazil

Study participating centre Faculty of Medical Sciences

Campinas SP Brazil 6111

Sponsor information

Organisation

State University of Campinas (Brazil)

ROR

https://ror.org/04wffgt70

Funder(s)

Funder type

University/education

Funder Name

State University of Campinas (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2011		Yes	No