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# Evaluation of rehabilitation in post-laryngectomy patients

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 19/02/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 13/03/2008 | Completed | [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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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 pharyngo-oesophageal 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

### Secondary study design
Non randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Screening

### Participant information sheet

### 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 measure
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.

### Secondary outcome measures
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.

### Overall study start date
10/03/2000

### 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

### Age group
Adult

### Sex

Both

### Target number of participants
20

### 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
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## Sponsor information

### Organisation
State University of Campinas (Brazil)

### Sponsor details
Disciplina de Otorrinolaringologia
Faculdade de Ciências Médicas

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**Sponsor type**
University/education

**ROR**
https://ror.org/04wffgt70

# Funder(s)

**Funder type**
University/education

**Funder Name**
State University of Campinas (Brazil)

# 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 | 01/11/2011 | | Yes | No |