

# Comparison between laser and diathermy assisted posterior cordotomy for bilateral vocal cord abductor paralysis

<b>Submission date</b> 27/02/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/03/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/01/2014	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Bilateral vocal cord paralysis (BVCP) is a potentially life threatening condition frequently requires surgical intervention called cordotomy. The objectives of treatment of BVCP are to achieve adequate airway and to preserve voice quality and laryngeal competence. The study compares two types of cordotomy.

### Who can participate?

All patients with BVCP for one year at least with a respiratory chink of a maximal width of 4 mm or less and who need cordotomy.

### What does the study involve?

Over a period of three years participants will be randomly allocated to one of two groups; Group (A) will be treated with laser assisted posterior cordotomy and Group (B) will be treated with diathermy assisted posterior cordotomy. The choice of the group will be decided by a process called randomisation, which is like a coin toss. During and at the end of the study, dyspnea severity, voice quality and aspiration will be assessed and compared between both groups.

### What are the possible benefits and risks of participating?

There will be mostly improvement of the airway. But there will be benefits to future best methods of treating BVCP.

The main risk of cordotomy is laryngeal edema, decrease quality of voice or aspiration. All patients will receive routine care, safety procedures to monitor airway and follow up for cordotomy.

### Where is the study run from?

This study was performed in Zagazig University Hospitals (Egypt).

### When is study starting and how long is it expected to run for?

The study lasted from February 2008 to February 2011 on 20 patients. Participants were for a period of two to three years.

Who is funding the study?  
Zagazig University Hospitals (Egypt)

Who is the main contact?  
Dr Mohammad Waheed El-Anwar  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Mohammad El-Anwar

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Comparison between laser and diathermy assisted posterior cordotomy for bilateral vocal cord abductor paralysis: a prospective randomized controlled trial

**Study objectives**  
It is hypothesised that the results of laser assisted posterior cordotomy will be better than diathermy assisted posterior cordotomy for bilateral vocal cord paralysis (BVCP) in regard to dyspnea severity, voice quality and aspiration.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Zagazig University Ethical Committee had approved this study and written formal consents had been signed by patients or their relatives

**Study design**

Prospective randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet Dr. Mohammad Waheed El-Anwar Address: Otorhinolaryngology, Head and Neck Surgery Department, Faculty of Medicine, Zagazig University, Egypt. Tel: 00201004695197 Email: mwenteg@yahoo.com

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

Optimum method of cordotomy

**Interventions**

Participants will be randomly categorized into two groups:

Group (A) will be treated with laser assisted posterior cordotomy

Group (B) will be treated with diathermy assisted posterior cordotomy

During and at the end of the study, dyspnea severity, voice quality and aspiration will be assessed and compared between both groups.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Dyspnea severity scale
2. Voice assessment protocol
3. Pearson aspiration scale

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/02/2008

**Completion date**

01/02/2011

## Eligibility

**Key inclusion criteria**

Patients [male and female, any age (no age limitation)] who are diagnosed as having bilateral abductor vocal cord paralysis for one year at least and maximal width of respiratory chink is 4 mm or less.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

20

**Key exclusion criteria**

1. Patients have unilateral vocal cord paralysis.
2. Patients who are diagnosed as having bilateral abductor vocal cord paralysis for less than one year duration.
3. Maximal width of respiratory chink is more than 4 mm.

**Date of first enrolment**

01/02/2008

**Date of final enrolment**

01/02/2011

## Locations

**Countries of recruitment**

Egypt

**Study participating centre**

Otorhinolaryngology, Head and Neck Surgery Department

Zagazig

Egypt

44519

# Sponsor information

## Organisation

Zagazig University (Egypt)

## Sponsor details

c/o Mohammad Waheed El-Anwar  
Otorhinolaryngology, Head and Neck Surgery Department  
Faculty of Medicine  
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## Sponsor type

University/education

## ROR

<https://ror.org/053g6we49>

# Funder(s)

## Funder type

University/education

## Funder Name

Zagazig University (Egypt) - Otorhinolaryngology, Head and Neck Surgery Department

# 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?
<a href="#">Results article</a>	results	01/09/2013		Yes	No