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

Submission date
27/02/2013

Recruitment status
No longer recruiting

Registration date
27/03/2013

Overall study status
Completed

Last Edited
06/01/2014

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 lee 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
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Sponsor information

Organisation
Zagazig University (Egypt)

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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?
Results article	results	01/09/2013		Yes	No