ISRCTN13454737 https://doi.org/10.1186/ISRCTN13454737

Efficacy of non-invasive ventilatory support in the physiotherapy treatment after pulmonary lobectomy

Submission date
27/01/2016

Recruitment status
No longer recruiting

Registration date
08/04/2016

Overall study status
Completed

Last Edited
08/04/2016

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Lung disease is a rising problem worldwide. Generally, lung disease can be broadly classified as cancerous or non-cancerous. Regardless of the type of disease, lung conditions generally experience problems with breathing and chest pain, as the diseased lung is not able to function properly. The human lungs are divided into sections called lobes. The right lung has three lobes and the left long has two lobes. A pulmonary lobectomy is an operation where one of the lobes of the lungs is removed (a bi-lobectomy is where two lobes are removed). This is an important procedure when only part of the lung is affected, as once the diseased lobe (or lobes) is removed the remaining lung tissue can work normally. The most common complications of a lobectomy are atelectasis (where part of the lung collapses) and pneumonia (a condition which involves swelling (inflammation) of the lung tissue). In order to try and prevent this, patients see a physiotherapist to learn deep-breathing and controlled coughing exercises in order to help the lungs to re-inflate after surgery and heal faster. cPAP (continuous positive airway pressure) and NIMV (non-invasive mechanical ventilation) are methods of non-invasive ventilatory (breathing) support which deliver air through a face mask in order to keep the airways open. Currently, these techniques are not really used in rehabilitation after a pulmonary lobectomy, although they could play a key role in the re-expansion of the lung. The aim of this study is to find out whether combining non-invasive ventilatory support and standard physiotherapy is more effective than standard physiotherapy alone after pulmonary lobectomy.

Who can participate?
Adults who are scheduled to have a pulmonary lombectomy or bi-lombectomy.

What does the study involve?
Following surgery, participants are randomly allocated to one of two groups. Participants in the first group are treated using cPAP for two hours a day for three days. If participants are having particular problems breathing (more than 30 breaths a minute), then they are treated using NIMV instead for the same amount of time. Participants in this group also receive three days of standard physiotherapy, which involves a series of breathing and walking exercises as well as assisted coughing (where the physiotherapist pushes on the chest during coughing to help bring

up mucus from the lungs). Participants in the second group receive standard physiotherapy only for the three days after their operation. At the start of the study and then again after 1 and 4 days, participants complete a breathing test to find out if their lung capacity (how much they can inhale) has increased. Participants also complete walking tests to judge how well they are recovering at 1 and 5 days after surgery.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to those taking part in this study.

Where is the study run from?
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico (Italy)

When is the study starting and how long is it expected to run for?
September 2012 to September 2016

Who is funding the study?
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico (Italy)

Who is the main contact?
Professor Mario Nossoti
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Efficacy of non-invasive ventilatory support in the physiotherapy treatment after pulmonary lobectomy

Study objectives
The use of non-invasive ventilatory support with standard physiotherapy is more effective than standard physiotherapy alone after pulmonary lobectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethicals Committee (Comitato Etico Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico Milano), 10/10/2012, ref: 2369

Study design
Prospective randomized controlled trial with post-interventional blinded evaluation

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.

Health condition(s) or problem(s) studied
Pulmonary neoplastic or non-neoplastic disease requiring pulmonary lobectomy or bi-lobectomy

Interventions
Patients are randomly divided in two groups in respect to postoperative physiotherapic treatment:

Intervention group: Participants are treated using continuous positive airway pressure (cPAP) (or non-invasive ventilation in case of respiratory rate is greater than 30 and/or PaCO2 is greater than 45 mmHg). This involves the cPAP (or NIV) delivery for 2 hours three times a day for 3 days. Participants in this group also receive standard physiotherapy.

Control group: Participants receive standard physiotherapy only.

Standard physiotherapy consists of:
1. Postoperative day (POD) 1: Maintaining the sitting position (at least 4 hours), walking (at least 30 minutes), assisted cough
2. POD 2: Maintaining the sitting position (at least 6 hours), walking (at least 90 minutes), assisted cough
3. POD 3: Maintaining the sitting position (at least 9 hours), walking (at least 180 minutes), assisted cough

Participants in both groups are followed up on postoperative days 1-5 and the length of their total hospital stay is recorded.

Intervention Type
Supplement

Primary outcome measure
1. Pulmonary volumes recovery is measured using the basal spirometry test at baseline, 1 and 4 days postoperatively
2. Total number of meters walked is measured using the 6 Minute Walking Test at baseline and 5 days postoperatively
3. Length of hospital stay is measured as the number of days from surgical operation to the discharge

Secondary outcome measures
1. Gas exchange improvement is measured using systemic arterial blood gas analysis at baseline, 1 and 4 days postoperatively
2. Post-operative complications are measured (in particular pneumonia and/or atelectasis documented by Chest X-Ray) through clinical observations throughout the postoperative period
3. Chest tube duration is measured as the number of days from operation to the removal of the last chest tube
4. Air leak is measured in liters per hours using a digital device of chest drainage at 1, 2, 3, 4 and 5 days postoperatively

Overall study start date
01/09/2012

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Aged between 18 and 78 years
2. Scheduled for pulmonary lobectomy or bi-lobectomy
3. Written informed consent obtenied

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Non aderhence or non-tolerating cPAP treatment
2. Need of mechanical ventilation beyond the postoperative day 1
3. Lack of physical ability to be treated by physiotherapy
4. Pulmonary complications after mechanical ventilation
5. Diagnosis of Obstructive Sleep Apnea Syndrome
6. Mini-Mental State Examination score of less than 20

Date of first enrolment
01/11/2012

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico
Via Francesco Sforza, 35
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Sponsor information

Organisation
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/016zn0y21

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

Results and Publications

Publication and dissemination plan
Planned publication in a Thoracic Surgery or Respiratory Journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository