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The effectiveness of physiotherapy breathing exercises after major chest surgery

Submission date
03/02/2012

Recruitment status
No longer recruiting

Registration date
10/05/2012

Overall study status
Completed

Last Edited
19/08/2015

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients receive routine chest physiotherapy following major chest surgery in order to prevent the development of chest infections, which lead to higher costs of hospital care and are the main cause of death following this type of surgery. The physiotherapy usually includes deep breathing exercises, which are thought to be necessary as areas of the lungs may be collapsed after surgery, and these exercises at regular intervals daily are thought to help re-open the lung. Deep breathing exercises can be performed through a plastic device which measures the size of the breath, known as an incentive spirometer. This is thought to improve the effectiveness of the exercises by motivating the patient to take the largest deep breaths possible.
Routine provision of physiotherapy following major chest surgery has long been recommended, and has recently been confirmed as beneficial following a large study which found a marked reduction in chest infection in patients who received treatment. Further research to identify who might most benefit from physiotherapy and exactly what interventions (for example incentive spirometry) are most beneficial is, however, still needed.
There is little quality evidence to support the widespread use of incentive spirometry following chest surgery; only two small studies have examined this treatment but demonstrated no benefit, perhaps because of the quality of the studies. Our aim was to examine the effectiveness of incentive spirometry as compared to deep breathing exercises in patients undergoing major chest and lung surgery at the regional thoracic surgery department at Heartlands Hospital, Birmingham (UK).
We also aimed to observe its effectiveness in patients specifically at a high risk of chest infection after surgery.

Who can participate?
Adults (aged 18 and over) undergoing planned major chest surgery involving the lungs.

What does the study involve?
Participants were randomly allocated to either the control group or the intervention group. Control group patients were asked to perform 'regular' deep breathing exercises (emphasising an active inspiration with a breath hold before a passive expiration), and the intervention group patients were asked to perform incentive spirometry, both starting the day after surgery.
The patients were asked to repeat their breathing exercises ten times at the daily physiotherapy

session, and encouraged to do this hourly on an independent basis. Treatment also included coughing, walking and shoulder exercises as per current UK practice. The patients continued to receive their treatment until hospital discharge. If any patient's condition required more treatment than described, it was given (for example assistance to clear mucus from the chest). Whilst the patients were in hospital they were also asked to wear a small plastic monitor attached to their upper arm with a velcro strap; this measured the amount of physical activity they were able to do from the day after surgery to the fourth day (this was similar to a simple pedometer).
To determine the success of the two treatments, the lung function of each patient was measured whilst still in hospital (with a simple blowing test), four days following surgery. This was compared to their pre-surgery lung function. If either group had a larger loss of lung function on the fourth day, it represented worse/slower recovery, and therefore lack of treatment benefit. The rate of chest infections and the length of hospital stay were also compared.

What are the possible benefits and risks of participating?
There have been no recorded complications of the breathing exercises to be examined. Reasons not to give incentive spirometry and adverse side effects are not widely documented, but it should not generally be used if the patient cannot be instructed properly, if patient co-operation is absent, or if the patient is unable to deep breathe. Possible complications could include over breathing (in the short term during treatment), pulmonary embolus, fatigue and airway tightening in asthmatics. The physiotherapists applying both regimens were aware to terminate treatment and take appropriate action if any such complications arose. Repetitions of the breathing exercises were performed with rests as necessary to avoid over breathing or fatigue. The treatments in this project were considered by an Ethics Committee and deemed suitable. As neither breathing exercise had yet been shown to be better than the other, no benefits of being allocated to either group were known. The information gained from this study was aimed to identify how best to treat patients in the future for their benefit.

Where is the study run from?
Birmingham Heartlands Hospital (UK).

When is the study starting and how long is it expected to run for?
The study started in October 2008 and finished in October 2010.

Who is funding the study?
West Midlands Strategic Health Authority & Birmingham Heartlands Hospital (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of a physiotherapy regimen that includes incentive spirometry post–thoracotomy

Study objectives
A physiotherapy regimen that includes incentive spirometry enhances recovery of lung function following thoracotomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Research Ethics Committee, 16/05/2008, ref: 08/H1207/79

Study design
Prospective open parallel design single-blind randomised 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

Health condition(s) or problem(s) studied
Thoracic surgery (lung resection)

Interventions
Control group subjects performed thoracic expansion exercises, and intervention group subjects incentive spirometry from postoperative day 1 (twice daily and subsequently once per day unless deemed necessary). Thoracic expansion exercises are deep breathing exercises emphasising active inspiration with a breath hold before a passive expiration. Incentive spirometry was performed with the Coach 2® device (Medimark Europe, Grenoble, France), again emphasizing maximal inspiration, with a breath hold. Breathing exercises were repeated ten times per session, and encouraged hourly on an independent basis. Treatment also included supported coughing, early mobilisation and active shoulder exercises as per current UK practice. Subjects continued to receive their allocated treatment until hospital discharge. If patient condition required escalation of treatment, in terms of frequency or intensity, this was not withheld.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Mean percentage drop in forced expiratory volume in one second (FEV1) on postoperative day 4 (expressed as a percentage of preoperative actual FEV1), as measured with Vitalograph spirometry equipment (Vitalograph, Buckingham, UK).

A blinded assessor performed spirometry; physiotherapy interventions were not provided by this assessor, neither was the assessor aware of group allocation.

Secondary outcome measures
Mean percentage ppo FEV1 achieved by postoperative day 4, frequency of postoperative pulmonary complication (PPC), postoperative length of stay (LOS), high dependency unit LOS, sputum retention as defined by need for insertion of 'rescue' minitracheostomy, intensive care unit (ICU) admission and in-hospital mortality. A scoring tool to assess frequency of PPCs amenable to physiotherapy was used daily (during physiotherapy assessment). PPC was recognised in the presence of 4 or more of the following variables; chest x-ray signs of atelectasis/ consolidation, elevated white cell count >11.2 x 109/L or administration of respiratory antibiotics, temperature >38ºC, positive signs of infection on sputum microbiology, oxygen saturation< 90% on room air, new/changed purulent sputum production (yellow or green), physician diagnosis of pneumonia or chest infection and re-admission or prolonged stay (over 36 hours) in ICU/HDU with problems which are respiratory in origin. This scoring tool was deemed appropriate for use in this study following comparison with other published scores.

Overall study start date

01/10/2008

Completion date
30/09/2010

Eligibility

Key inclusion criteria
Scheduled male and female patients, aged 18 or over, undergoing open thoracotomy with planned subsequent lung resection.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
186

Key exclusion criteria
Emergency thoracotomy, procedures involving the mediastinum and chest wall, planned lung resection via video-assisted thorocoscopic surgery, preoperative immobility, inability to perform spirometry or breathing exercises

Date of first enrolment
01/10/2008

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Heartlands Hospital
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
Heart of England NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.heartofengland.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
West Midlands Strategic Health Authority (UK)

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	27/09/2014		Yes	No