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Does the incentive spirometer decrease post-operative pulmonary complications and shorten hospital stay?

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 27/04/2018	**Condition category** Surgery	

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

N0557168271

Study information

Scientific Title
Does the incentive spirometer decrease post-operative pulmonary complications and shorten hospital stay? A randomised controlled trial

Study objectives
Does incentive spirometry in addition to standard physiotherapy decrease the incidence of post-operative pulmonary complications and shorten length of stay on High Dependency and total length of stay in hospital compared with traditional physiotherapy offered to post-operative patients who have undergone major abdominal surgery?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dudley Local Ethics Committee (UK), 03/08/2005, REC ref: 05/Q2702/30.

Study design
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 to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Abdominal

Interventions
360 patients undergoing major abdominal surgery, randomised to:
1. Traditional physiotherapy (180 patients)
2. Use of incentive spirometer and traditional physiotherapy (180 patients)

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
1. Length of stay on the High Dependency Unit
2. Length of hospital stay
3. Post operative pulmonary complications as judged by predefined criteria
4. Standard physiological observations
5. Antibiotic usage and indication for use
6. Chest x-ray findings
7. Number of physiotherapy contacts and time spent with each patient

Secondary outcome measures
No secondary outcome measures

Overall study start date
11/08/2005

Completion date
31/07/2009

Eligibility

Key inclusion criteria
All patients on surgical high dependency ward following abdominal surgery and able to understand and use the incentive spirometer

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
360

Key exclusion criteria
Patients who cannot understand and use the incentive spiromenter

Date of first enrolment
11/08/2005

Date of final enrolment
31/07/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Russells Hall Hospital
Dudley
United Kingdom
DY1 2HQ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
79 Whitehall
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SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The Dudley Group of Hospitals NHS Trust (UK), NHS R&D Support Funding

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