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Effect of early mobilisation on respiratory complications following abdominal surgery

Submission date 11/02/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/04/2008	**Overall study status** Completed	
Last Edited 26/04/2016	**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

Protocol serial number
sm110208/00

Study information

Scientific Title
Effect of post-operative early mobilisation on pulmonary complications and hospital stay: a randomised trial

Study objectives

Early mobilisation is used by many centres around the country, with physiotherapists hypothesising that movement will encourage deeper breaths due to increasing oxygen demand, improve muscle strength and patient confidence, reduce post-operative pulmonary complications (PPCs) and ultimately reduce length of stay. The aim of this study is to establish whether goal oriented early post-operative mobilisation would reduce post-operative pulmonary complications and reduce hospital length of stay in patients who have had elective abdominal surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending as of 12/02/2008: Ethics committee requires investigators to have registered with ISRCTN before considering their applications.

Primary study design
Interventional

Study design
Parallel-group, single blinded, single centre, randomised clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Elective upper and lower gastrointestinal (GI) surgery

Interventions
1. Control group: routine post-operative physiotherapy
2. Intervention group: routine post-operative physiotherapy and goal directed mobilisation

Patients will be encouraged to achieve progressive mobility goals as shown:
1. Up to sit out of bed
2. Mobilise 5 m assisted
3. Mobilise 20 m assisted
4. Mobilise 40 m independently

Each patient will be treated once each day, unless clinical need indicates further respiratory intervention. All patients will be reviewed for a minimum of 7 days post operatively, and until they have returned to their previous level of function.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
1. Post-operative pulmonary complications: both the number of patients with these complication and the severity will be taken into account

2. Pulmonary function tests: the forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) will be collected pre-operatively and post-operatively on days 3, 5 and prior to hospital discharge

Key secondary outcome(s)
1. HDU stay
2. Hospital stay

Completion date
01/05/2009

Eligibility

Key inclusion criteria
1. Elective patients
2 Abdominal surgery
3. Booked in High Dependency Unit (HDU)
4. Ability to give written informed consent prior to study participation
5 Male or female patients over 18 years old
6. Ability to communicate with the study personnel and to comply with the study requirements
7. Ability to mobilise (freely or with walking aid)
8. American Society of Anaesthesiologists (ASA) grade 1 - 3 inclusive

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Inability to communicate with the study personnel and to comply with the study requirements (mobility)
2. Unable to give consent
3. Under 18 years of age
4. Patients admitted to Intensive Care Unit (ICU) prior to HDU
5. Patients with impaired mobility (bed bound or wheel chair bound)
6. ASA grade 4 or above

Date of first enrolment
01/05/2008

Date of final enrolment
01/05/2009

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Dundee University and Medical School
Dundee
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Sponsor information

Organisation
University of Dundee (UK)

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration