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# Effect of early mobilisation on respiratory complications following abdominal surgery

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Mr Sami Shimi

**Contact details**
Dundee University and Medical School
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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.

## Study design
Parallel-group, single blinded, single centre, randomised clinical 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
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 measure
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

### Secondary outcome measures
1. HDU stay
2. Hospital stay

### Overall study start date
01/05/2008

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
200 (100 in each group - upper and lower GI surgery)

### 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
Scotland

United Kingdom

### Study participating centre
**Dundee University and Medical School**
Dundee
United Kingdom
DD1 9SY

## Sponsor information

### Organisation
University of Dundee (UK)

### Sponsor details
Ninewells Hospital
Ninewells Avenue
Dundee
Scotland
United Kingdom
DD1 9SY

### Sponsor type

University/education

**Website**
http://www.dundee.ac.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

**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