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Non-invasive ventilation (NIV) as an aid to rehabilitation in acute respiratory disease

Submission date 22/11/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/11/2010	**Overall study status** Completed	
Last Edited 15/05/2012	**Condition category** Respiratory	

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
V1

Study information

Scientific Title
Non-invasive ventilation (NIV) as an aid to rehabilitation in acute respiratory disease: A prospective, single-blind, randomised controlled trial

Study objectives

We wish to establish if it is feasible and effective to deliver NIV-assisted exercise, before the patient has recovered sufficiently to exercise in a conventional unassisted fashion, aiming to prevent loss of muscle function during acute admissions to hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by South West London Research Ethics Committee 1 on the 1st of November 2010 (ref: 10-H0801-44)

Study design
Prospective single blind randomised controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute exacerbation of chronic obstructive pulmonary disease (COPD)

Interventions
Patients will be randomised to one of three arms
1. Usual care
2. 1 hour per day of physiotherapy input including cycle exercise
3. 1 hour per day of exercise using NIV to support breathing

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Quadriceps strength measured as quadriceps isometric maximum voluntary contraction force using a dynamometer at 2 weeks after discharge.

Key secondary outcome(s))
1. COPD Assessment Test (CAT) score
2. St George's Respiratory Questionnaire (SGRQ)
3. Physical activity monitored with SenseWear armband
4. Acceptability of treatment
5. Incremental shuttle walk test distance
All secondary outcomes will be assessed at baseline, discharge from hospital and 2 weeks post discharge.

Completion date
01/06/2011

Eligibility

Key inclusion criteria
1. Adult patient admitted with an acute exacerbation of COPD
2. Expected to be in hospital for at least 24 hours

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients who are not expected to survive the admission
2. Patients with significant co-morbidity which is thought to be the major factor limiting their exercise capacity
3. Inability to understand instructions or use an exercise bike

Date of first enrolment
01/12/2010

Date of final enrolment
01/06/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Brompton Hospital
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
Imperial College London (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) Respiratory Biomedical Research Unit (BRU) (UK) - run jointly by:

Funder Name
Royal Brompton & Harefield NHS Foundation Trust (UK)

Funder Name
Imperial College London, National Heart & Lung Institute (NHLI) (UK)

Results and Publications

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	16/12/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes