

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

Submission date 22/11/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/11/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/05/2012	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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
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

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

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 measure

Quadriceps strength measured as quadriceps isometric maximum voluntary contraction force using a dynamometer at 2 weeks after discharge.

Secondary outcome measures

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.

Overall study start date

01/12/2010

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

Age group

Adult

Sex

Both

Target number of participants

45

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

England

United Kingdom

Study participating centre

Royal Brompton Hospital

London

United Kingdom

SW3 6NP

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

c/o Gary Roper

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Room G02

SAF Building

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Sponsor type

Not defined

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

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	16/12/2011		Yes	No