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Evaluation of the impact of a CoughAssist® mechanical in-exsufflator (MI-E) device on morbidity, quality of life and survival in patients with motor neurone disease (MND) using non-invasive ventilation (NIV)

Submission date	Recruitment status	[ ] Prospectively registered
12/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/04/2017	Mental and Behavioural Disorders	

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
5372

Study information

Scientific Title
Evaluation of the impact of a CoughAssist® mechanical in-exsufflator (MI-E) device on morbidity, quality of life and survival in patients with motor neurone disease (MND) using non-invasive ventilation (NIV)

Acronym
Evaluating CoughAssist

Study objectives
Without active management of respiratory symptoms, the majority of patients with motor neurone disease (MND) die within approximately 3 - 5 years, from neuromuscular respiratory failure. The applicants have previously shown that non-invasive ventilation (NIV) has a significant positive effect on the quality of life as well as prolonging the survival of MND patients, particularly in patients without severe bulbar dysfunction. However, increasing life expectancy by starting patients on NIV can uncover other downstream problems and a major problem for the patient is the inability to cough effectively. Poor cough can result in chest infections and airway blockage and pulmonary collapse. These problems lead to increasing respiratory failure and often require repeated hospital admissions.

The aim of the present study is to determine whether the use of a mechanical CoughAssist® device can reduce the symptoms of chest infections and therefore hospital admissions whilst improving the quality of life and survival of patients with MND who need to be started on using non-invasive ventilation (NIV). 40 MND patients who require NIV will be assigned to one of two groups via a process of minimisation. One cohort will be assigned to receive NIV and be taught how to use breath-stacking. The other cohort will be assigned to receive NIV and be given the use of a mechanical in-exsufflator (MI-E) (CoughAssist®) machine. Patients will be reviewed every 3 months for 1 year.

Outcome measures include the number of days with symptoms of chest infection, number of days in hospital due to chest infection, quality of life measures, measures of respiratory and neuromuscular function, survival of the patient and the impact of the intervention on the carer. Power calculations are based on the best information available in the literature regarding the number of days of hospitalisation expected for MND patients started on NIV. All outcome measures will be analysed by intention to treat; tests of significance will be two-sided.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 08/H1313/83

Study design
Single-centre randomised interventional prevention, process of care and treatment trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Motor neurone disease; Disease: Motor neurone disease

Interventions
CoughAssist® mechanical in-exsufflator versus breath stacking technique.

Study entry: single randomisation only

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Number of days with symptoms of chest infections requiring antibiotic therapy

Secondary outcome measures
1. Number of days in as a hospital inpatient due to chest infection
2. Quality of life (36-item short form health survey [SF-36])

Overall study start date
26/05/2009

Completion date
01/11/2011

Eligibility

Key inclusion criteria
1. The patient should not have any serious medical problems, apart from MND, which may reduce life expectancy
2. The patient should be capable of giving informed consent and should not have evidence of any significant impairment of cognitive function
3. Patients with MND in respiratory failure meeting two of the following criteria indicating the need for NIV:

3.1. Nocturnal or daytime hypercapnia (arterial blood gas [ABG] partial pressure of carbon dioxide in the blood [PaCO2] greater than 6.0 kPa)
3.2. Nocturnal hypoxaemia (oxygen saturation [SaO2] less than 88% for 5 consecutive minutes of the time asleep)
3.3. Lung function tests - forced vital capacity (FVC) less than 60% predicted
3.4. Maximal expiratory pressure less than 60 cm H2O
3.5. Orthopnoea
3.6. Symptoms of hypersomnolence or non-refreshing sleep
4. The patient should have a main carer who is willing to assist the patient in following the treatment regimen
5. The patient must fulfill the El Escorial clinically or laboratory supported probable or definite criteria for MND

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Planned sample size: 40; UK sample size: 40

Key exclusion criteria
1. Inability to tolerate NIV
2. Infringement of the contraindications of CoughAssist® (a history of bullous emphysema, susceptibility to pneumothorax or pneumo-mediastinum, or recent baratrauma)
3. Presence of a significant medical condition, other than MND, which may reduce life expectancy
4. Presence of significant impairment of cognitive function (for example, clinically overt fronto-temporal dysfunction which is clinically evident and noticeable to the family)
5. Participation in any other interventional trial

Date of first enrolment
26/05/2009

Date of final enrolment
01/11/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Royal Hallamshire Hospital
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Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.sth.nhs.uk/

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Research organisation

Funder Name
Motor Neurone Disease Association (UK) (ref: shaw/Apr08/6335)

Alternative Name(s)
MND Association, MNDA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No