

Sleep disordered breathing and the impact of nocturnal non-invasive ventilatory support on quality of life in motor neurone disease

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/12/2008	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RRCC804F res/1808/7002

Study information

Scientific Title

Study objectives

1. Early intervention with non-invasive ventilation will improve quality of life, survival and respiratory function in patients with motor neurone disease.
2. Domiciliary non-invasive ventilation in patients with motor neurone disease will not increase the strain experienced by the primary carer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Nervous system diseases: motor neurone disease

Interventions

1. Early intervention with non-invasive ventilation
2. Standard care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Quality of life

1. Generic instrument: Short Form 36
2. Specific instruments: Chronic Respiratory Disease Index, Sleep Apnoea Quality of Life Index, Epworth Sleepiness Scale

Secondary outcome measures

1. Survival
2. Impact on primary carer: Care Givers Strain Index
3. Hospital admissions
4. Respiratory function: Vital capacity, maximum static mouth pressures, sniff nasal inspiratory pressure

Overall study start date

10/01/2000

Completion date

10/01/2002

Eligibility

Key inclusion criteria

Patients with motor neurone disease under 75 years of age and without other serious illnesses.

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

Added December 2008: 102

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

10/01/2000

Date of final enrolment

10/01/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
NHS Northern & Yorkshire Regional Office
Newcastle upon Tyne
United Kingdom
NE2 4AB

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
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London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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	01/02/2006		Yes	No