

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/12/2008	<b>Condition category</b> 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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**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?
<a href="#">Results article</a>	results	01/02/2006		Yes	No