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

Submission date Recruitment status Prospectively registered 23/01/2004 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 23/01/2004 Completed [X] Results [ ] Individual participant data Last Edited Condition category Nervous System Diseases 08/12/2008

### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr Stephen Bourke

#### Contact details

NHS Northern & Yorkshire Regional Office Postgraduate Institute South Tyneside 10-12 Framlington Place Newcastle upon Tyne United Kingdom NE2 4AB +44 0191 284 311

## Additional identifiers

Protocol serial number 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 stain 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

#### Study type(s)

**Not Specified** 

#### 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(s)

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

#### Key secondary outcome(s))

- 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

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

**Not Specified** 

#### 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

United Kingdom

England

# 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)

# Funder(s)

#### Funder type

Government

#### Funder Name

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