

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

☐ Prospectively registered

☐ Protocol

Registration date

23/01/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

08/12/2008

Condition category

Nervous System Diseases

☐ Individual participant data

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 strain experienced by the primary carer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

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