ISRCTN88161562 https://doi.org/10.1186/ISRCTN88161562

Patterns of respiratory muscle involvement and the effects of respiratory muscle training in muscular dystrophy

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 02/11/2016	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr AJ Wills

Contact details
Clinical Neurology
University Hospital
Nottingham
United Kingdom
NG7 2UH
+44 (0)115 924 9924 (41141)
adewills61@hotmail.com

Additional identifiers

Protocol serial number
N0192122294

Study information

Scientific Title

Patterns of respiratory muscle involvement and the effects of respiratory muscle training in muscular dystrophy

Study objectives
We aim to determine the patterns of respiratory involvement in various inherited neuromuscular diseases. We will aim to quantify the utility of various parameters in assessing respiratory function and determine the measurements which might have reliable prognostic significance. These studies will be cross-sectional and longitudinal. In addition, in certain sub-groups we will undertake a randomised controlled trial to assess the effect of respiratory muscle training versus sham training. We will also aim to measure the effects of home oximetry and prophylactic antibiotics in patients with a low vital capacity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Queens Medical Centre

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory: Muscular dystrophy

Interventions
Case-control study and respiratory muscle training versus sham training RCT

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Respiratory function parameters
2. Time to require home ventilation
3. Mortality

Key secondary outcome(s)
No secondary outcome measures

Completion date
30/06/2007

Eligibility

Key inclusion criteria
Total number of subjects = 100; 80 with muscular dystrophy, 20 controls.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Added July 2008:
Patients already on ventilation, other neuromuscular conditions apart from inherited muscle diseases.

Date of first enrolment
12/09/2003

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospital
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Queens Medical Centre University Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration