

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/11/2016	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

1. Respiratory function parameters
2. Time to require home ventilation
3. Mortality

Secondary outcome measures

No secondary outcome measures

Overall study start date

12/09/2003

Completion date

30/06/2007

Eligibility

Key inclusion criteria

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

Participant type(s)

Mixed

Age group

Not Specified

Sex

Not Specified

Target number of participants

100

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

England

United Kingdom

Study participating centre
University Hospital
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Queens Medical Centre University Hospital NHS Trust (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