

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/11/2016	<b>Condition category</b> 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

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## 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