ISRCTN86814835 https://doi.org/10.1186/ISRCTN86814835

# Does neuromuscular electrical stimulation of the proximal leg muscles improve leg muscle endurance, exercise endurance and activity levels in people with lung cancer?

**Submission date**
29/09/2006

**Registration date**
29/09/2006

**Last Edited**
17/08/2012

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**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
N0192170447

# Study information

### Scientific Title

### Study objectives
Does neuromuscular electrical stimulation (NMES) of the thigh muscles of people with lung cancer improve muscle endurance, exercise endurance and physical activity levels as assessed by exercise on a Cybex machine, the endurance shuttle walking test (ESWT) and an ActivPal monitor respectively?

### 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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied
Cancer: Lung

### Interventions
A pilot study. Block randomisation to one of two groups.
Group 1: 4 weeks with NMES device
Group 2:- 4 weeks without device followed by 4 weeks with device

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Not provided at time of registration

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
02/11/2005

### Completion date
30/09/2007

## Eligibility

### Key inclusion criteria
16 people with non-small cell cancer and an East Oncology Group (EOG) performance status of 0 to 1 and who have lost less than 10% of their normal body weight.

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
16

### Key exclusion criteria
1. Pain or pathology limiting walking ability for the shuttle walking tests or limiting leg exercise on the cybex machine
2. History of ischaemic heart disease
3. Radiotherapy or chemotherapy in the previous 4 weeks as this may increase fatigue
4. Presence of a pacemaker - because the NMES device delivers a small electrical current, it is possible that this will interfere with the functioning of the pacemaker

### Date of first enrolment
02/11/2005

### Date of final enrolment
30/09/2007

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Hospital Palliative Care Team**
Nottingham
United Kingdom
NG7 2UH

# Sponsor information

**Organisation**
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

**Sponsor details**
The Department of Health, Richmond House, 79 Whitehall
London
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+44 (0)20 7307 2622
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**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
Queen's Medical Centre University Hospital NHS Trust (UK)

**Funder Name**
Nottingham Healthcare Trust (UK)

**Funder Name**
NHS R&D Support Funding

# 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

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/12/2009 | | Yes | No |