

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	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/08/2012	Condition category Cancer	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Hospital Palliative Care Team

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

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

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