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

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
17/08/2012

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

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

Study design
Randomised controlled trial

Primary study design
Interventional

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