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Is NeuroMuscular Electrical Stimulation an acceptable and feasible supportive therapy for patients with non-small cell lung cancer receiving palliative chemotherapy?

Submission date
06/11/2008

Recruitment status
No longer recruiting

Registration date
11/12/2008

Overall study status
Completed

Last Edited
27/07/2022

Condition category
Cancer

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/trial-neuromuscular-electrical-stimulation-nmes-non-small-cell-lung-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01097317

Secondary identifying numbers
1.0

Study information

Scientific Title
Is NeuroMuscular Electrical Stimulation an acceptable and feasible supportive therapy for patients with non-small cell lung cancer receiving palliative chemotherapy?: an open randomised phase II trial

Acronym
NMES

Study objectives
Primary: Is NMES an acceptable supportive therapy for patients with non-small cell lung cancer undergoing at least 3 cycles of palliative chemotherapy?
Secondary:
i) Is NMES a safe intervention to offer patients undergoing palliative chemotherapy?
ii) To what extent does 3 cycles of palliative chemotherapy impact on leg muscle strength, body composition and physical activity levels in patients with NSCLC and can the use of NMES influence these changes?
iii) What is the rate of recovery or decline in these parameters following cessation of 3-4 cycles of chemotherapy and can the use of NMES influence this?
iv) What are patients attitudes about the use of NMES during chemotherapy?

As of 24/02/2011 the anticipated end date for this trial has been updated from 01/02/2011 to 01/02/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham 1 REC on 21/04/2009 (ref: 9/H0403/24)

Study design
Open randomised controlled phase II 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Non-small cell lung cancer

Interventions
Participants will be randomly allocated (1:1 allocation ratio) to receive one of the following treatment regimen(s):

Control arm: Three to four cycles of first line palliative chemotherapy with carboplatin /vinorelbine administered as part of usual care by Nottingham University Hospital NHS Trust staff. Each chemotherapy cycle is planned to last for 21 days and consists of an administration of vinorelbine and carboplatin (day 1 of cycle) and a second administration of vinorelbine one week later (day 8 of cycle).

Intervention arm:
The palliative chemotherapy described above plus NMES.

NMES programme:
NMES for 30 min daily at home to the anterior thighs throughout chemotherapy. Because patients are generally anxious about starting chemotherapy we will defer initiating NMES until one week after commencing cycle one. A physiotherapist will supervise the first session of NMES either at hospital or in the patient's home depending on patient preference. This will be supplemented by written instructions, weekly phone calls and home visits if required. Stimulation will be delivered using a MicroStim Exercise Stimulator MS2v2 (Odstock Medical Ltd, UK) and self-adhesive electrodes placed over the body of the quadriceps. The intensity or amplitude (device output 0-120 mA, tested across 1,000 ohm) will initially be set to elicit a visible and comfortable muscle contraction. Thereafter, patients will be encouraged to increase the amplitude as tolerated during the monitoring phone calls. The proportion of the treatment duration which is active, i.e. the stimulation is on, will increase on a weekly basis from 11% to 18% to 25%, remaining constant thereafter.

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Intervention Type
Other

Phase
Phase II

Primary outcome measure
Adherence to NMES: Proportion of patients completing a pre-determined level of compliance to the recommended NMES programme (NMES for 30 min three times a week) measured using a self-report daily diary.

The primary and secondary outcomes will be assessed at baseline, end of treatment at week 9 or 12 (depending on 3 or 4 chemotherapy cycles), follow-up assessments at week 17 or 20 (depending on 3 or 4 chemotherapy cycles).

Secondary outcome measures
1. Safety of NMES: real-time adverse event reporting using the Common Terminology Criteria for Adverse Events (CTC AE) v3.0
2. Quadriceps muscle strength: peak torque (Nm) measured using a portable Manual Muscle Tester® dynamometer (Lafayette Instruments, USA)
3. Body composition: lean tissue mass of the body and thighs (kg) assessed by low-dose dual energy x-ray absorptiometry (DEXA)
4. Physical activity level: mean daily step count assessed by a small, lightweight activPAL™ accelerometer worn on the thigh for one week
5. Response to chemotherapy: overall objective clinical response categorised using Response Evaluation Criteria In Solid Tumours, documented from patients' medical reports
6. Nutritional intake: mean daily energy (kJ/d) and protein (g/d) intake estimated from a 3-day food and drink diary
7. Fatigue: Multidimensional Fatigue Inventory
8. Quality of life: the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30) and the lung cancer specific module EORTC QLQ-LC13

The primary and secondary outcomes will be assessed at baseline, end of treatment at week 9 or 12 (depending on 3 or 4 chemotherapy cycles), follow-up assessments at week 17 or 20 (depending on 3 or 4 chemotherapy cycles).

Overall study start date
01/02/2009

Completion date
01/02/2012

Eligibility

Key inclusion criteria
1. Both males and females, 16 years or over
2. Informed consent
3. Histological diagnosis of NSCLC
4. Eastern Collaborative Oncology Group (ECOG) Performance Status of 0, 1 or 2
5. Scheduled to receive 3-4 cycles of first line palliative chemotherapy with carboplatin /vinorelbine

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
52

Total final enrolment
49

Key exclusion criteria
1. Implanted cardiac pacemaker
2. Epilepsy
3. Spinal cord pathology
4. Pregnancy

Date of first enrolment
01/02/2009

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Wales Cancer Trials Unit
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Sponsor information

Organisation
Cardiff University (UK)

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Sponsor type
University/education

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ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Other

Funder Name
National Cancer Research Institute (NCRI) Supportive and Palliative Care (SuPaC) Research Collaboration (UK) (ref: LCSuPaC 35)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	30/12/2013		Yes	No
Plain English results			27/07/2022	No	Yes