

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/12/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/07/2022	Condition category Cancer	<input type="checkbox"/> 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

Contact name

Miss Helen Phillips

Contact details

Wales Cancer Trials Unit
School of Medicine
Cardiff University
6th Floor, Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom
CF14 4YS
+44 (0)29 2068 7461
helen.phillips@wctu.wales.nhs.uk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT01097317

Protocol serial number

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

Study type(s)

Treatment

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.

Contact details of Principal Investigator:

Dr Andrew Wilcock

Hayward House Macmillan Specialist Palliative Cancer Care Unit

Nottingham University Hospitals NHS Trust

City Hospital Campus

Hucknall Road

Nottingham

NG5 1PB

United Kingdom

Email: andrew.wilcock@nottingham.ac.uk

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

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).

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Cardiff

United Kingdom

CF14 4YS

Sponsor information

Organisation

Cardiff University (UK)

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

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