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NOURISH: Phase II Trial

Submission date	Recruitment status	[_] Prospectively registered
14/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/06/2014	Musculoskeletal Diseases	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-see-taking-supplement-powder-helps-improve-weight-muscle-loss-people-lung-cancer-nourish

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
LU2005

Study information

Scientific Title
Improving the management of cachexia in patients with advanced lung cancer: does the introduction of beta-hydroxy beta-methylbutyrate / arginine / glutamine (HMB/ARG/GLN) supplementation maintain lean body mass and quality of life?

Acronym

NOURISH

Study objectives
This is a phase II trial. The outcome will not, in itself, be interpreted to guide clinical management. The intention is to detect a signal that intervention using HMB/ARG/GLN supplementation alters the rate of change in LBM (used as a more meaningful measurement of cachexia than weight) sufficiently to justify further investigation in a Phase III trial. Other outcomes attributable to cachexia such as loss of muscle strength and deterioration in functional status and QoL will be measured as secondary endpoints. A Phase III trial will formally test the hypothesis that the intervention results in clinical benefit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Black Country Research Ethics Committee Ref: 11/WM/0071 07 April 2011

Primary study design
Interventional

Study design
Prospective, multicentre, Phase II, two arm, double-blinded, placebo-controlled randomised clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Management of cachexia in advanced lung cancer

Interventions
Patients will receive either beta-hydroxy beta-methylbuyrate/arginine/glutamine (HMB/ARG /GLN) or a matched placebo as 1 sachet twice daily twice daily for 12 weeks

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Beta-hydroxy beta-methylbuyrate/arginine/glutamine (HMB/ARG/GLN)

Primary outcome(s)
The number of patients who are alive without significant loss of lean body mass (LBM) (i.e. not more than 5%)

Key secondary outcome(s)
1. Change in LBM measured by Bioelectrical Impedance Analysis (BIA) after 12 weeks of HMB /ARG/GLN or a matched placebo compared to baseline
2. Lean body mass (LBM) at 3 weekly intervals from start of HMB/ARG/GLN/placebo intervention

for 12 weeks
3. Functional status will be assessed by handgrip strength measured at each trial visit using the Jamer™ dynamometer
4. Change in QoL measured by the FAACT questionnaire from baseline to week 12

Completion date
01/05/2013

Eligibility

Key inclusion criteria
1. Newly diagnosed small cell lung cancer (SCLC) or non small cell lung cancer (NSCLC)
2. Able to take oral nutrition
3. WHO performance status 0-2
4. Life expectancy greater than 4 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients suitable for radical treatment with curative intent
2. Patients who have already commenced first line chemotherapy or radiotherapy
3. Patients for whom the diagnosis of lung cancer was made more than 8 weeks before trial entry
4. Known or suspected to be pregnant
5. Patients with pacemaker or internal defibrillator in situ

Date of first enrolment
01/05/2011

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Oncology
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research organisation

Funder Name
National Cancer Research Institute (NCRI)

Funder Name
Supportive and Palliative Care (SuPaC) Research Collaborative grant (LCSuPaC 30)

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?
Abstract results	abstract e20684	01/07/2014		No	No