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NOURISH: Phase II Trial

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

Contact name
Dr Joyce Thompson

Contact details
Department of Oncology
Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Prospective, multicentre, Phase II, two arm, double-blinded, placebo-controlled randomised clinical 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
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 measure
The number of patients who are alive without significant loss of lean body mass (LBM) (i.e. not more than 5%)

Secondary outcome measures
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

Overall study start date
01/05/2011

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

Age group
Adult

Sex
Both

Target number of participants
96

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
England

United Kingdom

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

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 414 3789
NOURISH@trials.bham.ac.uk

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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