

NOURISH: Phase II Trial

Submission date 14/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/05/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/06/2014	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

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Contact details

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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

Study design

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

Primary study design

Interventional

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-methylbutyrate/arginine/glutamine (HMB/ARG/GLN) or a matched placebo as 1 sachet twice daily for 12 weeks

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Beta-hydroxy beta-methylbutyrate/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