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A pilot trial of energy-dense supplements in malnourished patients

Submission date	Recruitment status
30/05/2007	No longer recruiting
Registration date	**Overall study status**
22/06/2007	Completed
Last Edited	**Condition category**
22/10/2010	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NCC100

Study information

Scientific Title

Study objectives
Investigate the role of energy-dense supplements in the management of patients with malnutrition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Bath Local Research Ethics Committee on the 22nd March 2007 (ref: 07/Q2001/46).

Study design
Prospective, interventional, randomised, parallel, three-arm study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Malnutrition in the elderly

Interventions
The interventions are:
1. Standard dietary care
2. A high-energy supplement
3. A high energy supplement plus micronutrients

Duration: four weeks
Dosage: 400 kcal/day
Follow-up: patients are taking part in the trial for four weeks only. There is no further follow up.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Energy-dense supplementation

Primary outcome measure
Nutrient intake, assessed by diet diary at weeks one, two and four.

Secondary outcome measures
1. Gastro-Intestinal (GI) tolerance, using Bristol Stool Chart at weeks one, two and four
2. Product compliance, by daily questionnaire throughout the four weeks and product acceptability by questionnaire in weeks two and four
3. Appetite, measured in weeks one and four by questionnaire
4. Anthropometry (weight and Body Mass Index [BMI]), measured in weeks one, two and four
5. Muscle function, measured by hand grip dynamometry in weeks one and four
6. Quality of Life, measured using EuroQol EQ-5D questionnaire in weeks one and four
7. Blood lipids and micronutrients, measured in in weeks one and four
8. Safety, falls assessment measured using Berg Balance Scale at weeks one and four

Overall study start date
04/06/2007

Completion date
30/12/2007

Eligibility

Key inclusion criteria
1. Male or female
2. Aged greater than 50 years
3. At risk of malnutrition
4. Competent to provide written informed consent and able to answer questions
5. No requirement for tube or parenteral feeding
6. Willingness to take part in the trial and to follow the trial protocol

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
75

Key exclusion criteria
1. Requirement for tube or parenteral nutrition
2. Patients receiving palliative care
3. Patients with chronic renal disease requiring dialysis

4. Patients with liver failure
5. Participation in other studies
6. Taking a supplement in the last four weeks

Date of first enrolment
04/06/2007

Date of final enrolment
30/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nutricia Clinical Care
Wiltshire
United Kingdom
BA14 0XQ

Sponsor information

Organisation
Nutricia Clinical Care (UK)

Sponsor details
White Horse Business Park
Trowbridge
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United Kingdom
BA14 0XQ

Sponsor type
Industry

Website
http://www.nutricia-clinical-care.co.uk/asp/show_subject.asp

ROR
https://ror.org/007hfqg84

Funder(s)

Funder type
Government

Funder Name
Nutricia Clinical Care (UK)

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?
Results article		15/07/2008		Yes	No