A pilot trial of energy-dense supplements in malnourished patients

Submission date Recruitment status Prospectively registered 30/05/2007 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 22/06/2007 Completed [X] Results Individual participant data **Last Edited** Condition category 22/10/2010 Nutritional, Metabolic, Endocrine

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 Wiltshire 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