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A randomised double-blind placebo-controlled study of energy, protein and micronutrients supplementation of elderly patients in active rehabilitation settings

Submission date
12/09/2002

Recruitment status
No longer recruiting

Registration date
12/09/2002

Overall study status
Completed

Last Edited
08/06/2011

Condition category
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
577/484

Study information

Scientific Title

Acronym
FED Trial

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind placebo-controlled 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
Nutritional status in the elderly

Interventions
Elderly patients referred for an active period of rehabilitation following an episode of acute illness are randomised to:
1. Normal hospital diet plus placebo, or
2. Normal hospital diet plus oral supplements for 6 weeks

Normal diet is what is normally provided to patients. All patients will have nutritional supplements or placebo prescribed in their drug charts. The supplement group will receive a

daily oral nutritional supplement 400 ml or more given daily at 15.00 and 20.00 hours in addition to the standard hospital diet. The composition of the supplement is such as to provide between 100 - 150% of the Reference Nutrient Intakes for a healthy old person for the following nutrients: carbohydrates, protein, fat, vitamins (A, C, D, E, B1, B2, B6, B12, folic acid, niacin, biotin and pantothenic acid), and minerals (potassium, magnesium, calcium, phosphorous, chloride, iron, zinc, iodine, copper, manganese and selenium).

Supplementation will continue for a period of 6 weeks. This will be either entirely in hospital or in the community also for patients discharged earlier than 6 weeks. For those discharged earlier than 6 weeks supplies will be given for patients to take in the community and they or their carers will be shown how to fill in food diary cards for the remaining period. The placebo will be identical to the supplement but will contain no protein or micronutrients and with a minimum calorie content in it to make it tasty and palatable to patients. Different flavours of supplements and placebo will be prepared and tested initially in a pilot study and those most liked by patients will be made available for patients to choose from.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nutritional supplements

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

Completion date
01/01/2003

Eligibility

Key inclusion criteria
Patients will be eligible for the study if they meet the following criteria:
1. Age 65 years, stable medical condition, referred for an active rehabilitation program
2. Able to swallow
3. Able to sign an informed written consent form

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
445

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2000

Date of final enrolment
01/01/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Institute for Studies on Ageing
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
The Health Foundation (UK)

Sponsor details
90 Long Acre
London
United Kingdom
WC2E 9RA
+44 (0)20 7257 8000
info@health.org.uk

Sponsor type
Charity

Website

http://www.pppfoundation.org.uk/

ROR
https://ror.org/02bzj4420

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation (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	results	01/07/2006		Yes	No