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Effects of oral nutritional supplements compared to fortified foods on energy and protein intake in undernourished geriatric inpatients

Submission date
24/09/2012

Recruitment status
No longer recruiting

Registration date
03/10/2012

Overall study status
Completed

Last Edited
09/11/2015

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether energy-dense small-volume oral nutritional supplements (ONS) are more effective than fortified food at helping hospitalized elderly people reach their recommended energy and protein intakes.

Who can participate?
Geriatric inpatients who are undernourished or at risk of undernutrition.

What does the study involve?
Participants are randomly allocated to either receive energy-dense small-volume oral nutritional supplements or fortified foods.

What are the possible benefits and risks of participating?
Possible benefits are increased nutritional intake resulting in improved nutritional, functional and clinical outcomes.

Where is the study run from?
Department of Geriatric Medicine, Medical centre Leeuwarden (Netherlands)

When is study starting and how long is it expected to run for?
November 2009 to May 2010

Who is funding the study?
Nutricia Netherlands BV and Danone Research, Centre for Specialised Nutrition (Netherlands)

Who is the main contact?
Dr DZB van Asselt

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Effects of oral nutritional supplements compared to fortified foods on energy and protein intake in undernourished geriatric inpatients: a randomised controlled trial

Study objectives
In between meals, energy dense, small volume oral nutritional supplements (ONS) are more effective than fortified food to reach recommended energy and protein intakes in hospitalized elderly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Assessment Patient Research (Regionale Toetsingscommissie Patiengebonden Onderzoek) (RTPO), 12/10/2009, ref: TPO 648

Primary study design
Interventional

Study design
Parallel two arms randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malnutrition

Interventions

Intervention group: Energy dense, small volume oral nutritional supplements
Control group: fortified foods

Duration of intervention: during hospitalisation until discharge.

Intervention Type
Supplement

Primary outcome(s)
Number of patients achieving an extra intake of 450 kcal per day

Key secondary outcome(s)
1. Recommended energy and protein intakes
2. Length of hospital stay
3. Antibiotic usage

Completion date
15/05/2010

Eligibility

Key inclusion criteria
Risk of malnutrition (MNA-sf score 8-11) or malnutrition (MNA-sf score <7)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Terminal illness
2. Expected death during hospitalization / palliation
3. Hospital stay shorter than 14 days
4. Incomplete patient files
5. Need for tube feeding
6. A nothing per mouth order

Date of first enrolment
01/11/2009

Date of final enrolment
15/05/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Medical Centre Leeuwarden
Leeuwarden
Netherlands
8901 BR

Sponsor information

Organisation
Medical Centre Leeuwarden (Netherlands)

ROR
https://ror.org/0283nw634

Funder(s)

Funder type
Industry

Funder Name
Nutricia Research Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Funder Name
Danone Research Centre for Specialised Nutrition

Alternative Name(s)
Danone Research, Center for Specialised Nutrition, Center for Specialized Nutrition, Centre for Specialised Nutrition of Danone Research

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration