

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	<input type="checkbox"/> Prospectively registered
Registration date 03/10/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/11/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

Dr Dienneke van Asselt

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design

Parallel two arms randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Number of patients achieving an extra intake of 450 kcal per day

Secondary outcome measures

1. Recommended energy and protein intakes
2. Length of hospital stay
3. Antibiotic usage

Overall study start date

01/11/2009

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

Age group

Senior

Sex

Both

Target number of participants

108

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)

Sponsor details

c/o Dieneke van Asselt

Department of Geriatric Medicine

Postbus 888

Leeuwarden

Netherlands

8901 BR

Sponsor type

Hospital/treatment centre

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

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