

# Evaluation of compliance with two different ONS formats in hospitalised geriatric patients with (or at risk of) malnutrition.

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The aim of this study is to evaluate compliance with two different ONS formats in hospitalised geriatric patients with (or at risk of) malnutrition.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Appetite and general nutritional disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON35352

### Source

ToetsingOnline

### Brief title

ECLIPS

### Condition

- Appetite and general nutritional disorders

### Synonym

malnutrition

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Danone Research - Centre for Specialised Nutrition

**Source(s) of monetary or material Support:** Danone Research

## Intervention

**Keyword:** compliance, geriatrics, ONS

## Outcome measures

### Primary outcome

Compliance

### Secondary outcome

Energy and protein intake

## Study description

### Background summary

In a wide variety of hospital and community patients, the use of oral nutritional supplements (ONS) has been shown to significantly improve energy and nutrient intake, body weight and functional outcomes in comparison with routine clinical care (Stratton, 2003). To benefit from the effects of ONS it is of great importance that patients comply with the prescribed nutrition regimen, to ensure that nutritional intake is optimal and requirements are met.

### Study objective

The aim of this study is to evaluate compliance with two different ONS formats in hospitalised geriatric patients with (or at risk of) malnutrition.

### Study design

This is a single centre, observational study.

### Study burden and risks

None. This is an observational study. Patients receive care-as-usual.

## Contacts

### Public

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)  
Elderly (65 years and older)

### Inclusion criteria

- Age  $\geq$  65 years
- Malnourished or at risk of malnutrition (MNA total score  $\leq$  23.5)
- Prescription for 2 bottles of ONS per day according to the interdisciplinary protocol of the geriatric ward

### Exclusion criteria

- Expected hospital stay shorter than 8 days
- Terminal illness
- Expected death during hospitalization/palliation
- Need for tube feeding or parenteral feeding

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2011
Enrollment:	100
Type:	Actual

## Ethics review

Approved WMO	
Date:	28-09-2011
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

**Other (possibly less up-to-date) registrations in this register**

No registrations found.

**In other registers**

Register	ID
CCMO	NL37633.099.11