

# Transmural Nutritional Support

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 13/05/2013	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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**  
NTR476

## Study information

**Scientific Title**

**Study objectives**

To study the cost-effectiveness of transmural nutritional support (from admission to hospital until 3 months after discharge) in malnourished elderly patients, compared to usual care.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised open label active controlled parallel group trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet****Health condition(s) or problem(s) studied**

Malnutrition

**Interventions**

Usual nutritional care versus oral nutritional supplements (600 kcal/day) from admission to hospital until 3 months after discharge.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. Changes in ADL, functional limitations, muscle strength, quality of life
2. Length of hospital stay, number of re-admissions to hospital, complication rate, number of medical prescriptions and number of doctor contacts within the first 3 months after discharge
3. Economic evaluation

**Secondary outcome measures**

Changes in body weight, body composition

**Overall study start date**

01/01/2006

**Completion date**

31/12/2009

## Eligibility

**Key inclusion criteria**

1. Hospitalised patients of 60 years and over with a BMI <20 and/or involuntary weight loss >10% (= malnourished)
2. Admitted to the departments of internal medicine
3. Gastroenterology
4. Nephrology
5. Rheumatology
6. Dermatology

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

164

**Key exclusion criteria**

1. Well-nourished
2. Decreased consciousness
3. Inability to speak the Dutch language
4. Expected length of hospital stay <2 days

**Date of first enrolment**

01/01/2006

**Date of final enrolment**

31/12/2009

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

**VU University Medical Center**  
Amsterdam  
Netherlands  
1007 MB

## Sponsor information

### Organisation

Vrije University Medical Centre (VUMC) (Netherlands)

### Sponsor details

Van der Boechorststraat 7  
Amsterdam  
Netherlands  
1081 BT

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/00q6h8f30>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

### Alternative Name(s)

Netherlands Organisation for Health Research and Development

### 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	10/02/2010		Yes	No
<a href="#">Results article</a>	results	01/05/2011		Yes	No
<a href="#">Results article</a>	results	01/12/2012		Yes	No