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Transmural Nutritional Support

Submission date	Recruitment status	[_] Prospectively registered
27/01/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/05/2013	Nutritional, Metabolic, Endocrine	

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?
Protocol article	protocol	10/02/2010		Yes	No
Results article	results	01/05/2011		Yes	No
Results article	results	01/12/2012		Yes	No