

Transmural Nutritional Support

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr M.A.E. van Bokhorst - de van der Schueren

Contact details

VU University Medical Center
Department of Nutrition and Dietetics
P.O. Box 7057
Amsterdam
Netherlands
1007 MB
m.vanbokhorst@vumc.nl

Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s))

Changes in body weight, body composition

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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)

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

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