Transmural Nutritional Support.

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21262

Bron
NTR

Verkorte titel
N/A

Ondersteuning

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective(s) / research question(s):
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.

Study design:
Randomised Clinical Trial

Study population:
Hospitalised patients of 60 years and over admitted to the wards of mixed internal medicine with a BMI<20 and/or involuntary weight loss >10%(= malnourished).

Intervention:
Standardised Oral Nutritional Support (600 kcal/day) from admission untill three months after discharge versus usual care

Outcome measures:

Primary:

- Changes in ADL, functional limitations, muscle strength and quality of life between admission and at 3 months after discharge.

- 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.

Secondary:

- Changes in body-weight and composition between admission and at 3 months after discharge.

Power/data analysis:
100 Control and 100 intervention patients are needed in order to detect a clinically relevant difference of 20% in functional and nutritional status or a difference in complication rates of 40% (control) vs. 20% (intervention). Intention-to-treat analysis. Multivariate techniques to test differences between intervention and control group. Regression analysis to test the relative contribution of the intervention on the outcome parameters.

Economic evaluation:
Cost-effectiveness ratios and cost-utility ratios will be calculated with bootstrapping according to the bias corrected percentile method.

Keywords:
malnutrition, transmural, elderly, nutritional support

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

Usual nutritional care vs. oral nutritional supplements from admission to hospital under 3 months after discharge.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Malnourished older patients (>60y);
2. Admitted to the departments of internal medicine;

3. Gastroenterology;
4. Nephrology;
5. Rheumatology;
6. Dermatology.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Well-nourished;
2. Descreased consciousness;
3. Inability to speak the Dutch language;
4. Expected Length of Hospital Stay <2 days.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2006
Aantal proefpersonen:	164
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL436
NTR-old	NTR476
Ander register	: N/A
ISRCTN	ISRCTN29617677

Resultaten

Samenvatting resultaten
N/A