

Randomized Controlled Trial to the effectiveness of Oral Nutrition Supplementation during Medical Rounds in the Hospital.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24194

Source

NTR

Health condition

Oral Nutritional Supplement
Medical Rounds
Malnutrition
Hospital

Sponsors and support

Primary sponsor: Deventer ziekenhuis

N. Bolkesteinlaan 75
7416 SE Deventer
tel. 0570 - 53 53 53

Source(s) of monetary or material Support: Deventer ziekenhuis

Intervention

Outcome measures

Primary outcome

Proportion patients who received their treatment goal.

Secondary outcome

Intake in ml. Nurses and food assistants read the amount of ONS left in the bottles. Interrater reliability is evaluated with ICC.

Study description

Background summary

Randomised Controlled Trial to the effectiveness of Oral Nutrition Supplementation (ONS) during Medical Rounds in the Hospital. The aim of this study is to compare the effect of ONS during medical rounds on nutrient intake in patients who suffer severe disease related malnutrition and evaluate the effect of low doses/high frequency on this nutrient intake. Therefore 300 patients from six hospital wards (internal and surgical) will be allocated at random in one of three treatment groups: 1. ONS in between meals twice a day a whole bottle of 125 ml at 10.00 and 15.00, or 2. ONS during medical rounds twice a day a whole bottle of 125 ml at 12.00 and 17.00 or 3. ONS during medical rounds four times a day half a dose of 62 ml at 8.00-12.00-17.00-20.00 hour). Follow-up is use of ONS during hospital stay or as long as ONS is indicated (max. 30 days). Primary endpoint is percentage patients who receive their treatment goal (e.g. 75% intake). Secondary endpoint is intake of ONS in ml.

Study objective

ONS during medical rounds improves the intake in malnourished patients.

Study design

Moments of consumption. Patients have 1 hour to finish their ONS.

Intervention

1. ONS in between meals twice a day a whole bottle of 125 ml at 10.00 and 15.00;
2. ONS during medical rounds twice a day a whole bottle of 125 ml at 12.00 and 17.00;
3. ONS during medical rounds four times a day half a dose (e.g. 62 ml) at 8.00-12.00-17.00-20.00.

All three groups use ONS during hospital stay or as long as ONS is indicated (max. 30 days).

Intake in ml will be assessed to evaluate proportion of patients who received their treatment goal (e.g. 75% intake of prescription).

Contacts

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Eligibility criteria

Inclusion criteria

Adult malnourished patients in Deventer Hospital diagnosed with SNAQ screening tool or diagnosed by physician and treated by oral nutritional supplementation.

Exclusion criteria

1. Hospital wards: Paediatrics, obstetrics, ICU, ER, dialysis, chemotherapy, X-ray;
2. Patients with enteral or parenteral nutrition;
3. Patients with swallow disabilities;
4. Patients with (pre)dialysis therapy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-04-2010
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion	
Date:	25-09-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34788
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2426
NTR-old	NTR2535
CCMO	NL31647.075.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34788

Study results

Summary results

N/A