Timing of PEG tube placement in patients with amyotrophic lateral sclerosis: soon or later?

No registrations found.

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

Summary

ID

NL-OMON26494

Source
NTR

Health condition

Patients with Amyotrophic Lateral Sclerosis (ALS) and dysphagia

Sponsors and support

Source(s) of monetary or material Support: The study is funded by the Prinses Beatrix Fund, The Hague, The Netherlands

Intervention

Outcome measures

Primary outcome

Survival

Secondary outcome

1. Vital capacity;
2. BMI;

3. Triceps skinfold;
4. ALSFRS;
5. VAS Q0L;
6. SF 36;

Study description

Background summary

ALS patients with dysphagia tend to delay a PEG procedure, sometimes with evident impact on nutritional status. Nutritional status is known to be in independent prognostic factor for survival in ALS. PEG procedures in ALS patients with compromised vital capacity is not without risk. In a randomised controlled trial we include ALS patients with dysphagia (Hillel score 7 or 8) and vital capacity >65%. In arm 1 patients receive a PEG within 1 month after inclusion, in arm 2 patients wait untill either VC falls below 55%, or Hillel score is 4 or 5, or any other moment that they decide for themselves to have a PEG placed. Effects of these two strategies on survival, nutritional and functional status, and quality of life are investigated. Follow-up is 15 months.

Study objective

Early PEG placement in ALS patients with dysphagia is associated with longer survival, better nutritional and functional status, and better quality of life

Intervention

Early PEG (PEG placement within 4 weeks after inclusion) versus a "wait and see approach", with probably a PEG placement at a later stage

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Eligibility criteria

Inclusion criteria

1. Patients with possible, probable, probable lab supported, or definite ALS;
2. Dysphagia Hillel score 7 or 8 (ALSSS dyspagia subscale);
3. Vital capacity >65%;
4. Age > 18 yr and < 85 yr;
5. Informed consent.

Exclusion criteria

1. Contra-indication for PEG

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-08-2004
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-01-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL857
NTR-old	NTR871
Other	: N/A
ISRCTN	ISRCTN63827964

Study results

Summary results
N/A