

Timing of percutaneous endoscopic gastrostomy tube placement in patients with amyotrophic lateral sclerosis: sooner or later?

Submission date 08/02/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 08/02/2007	Overall study status Completed	☐ Protocol
Last Edited 20/08/2021	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL857 (NTR871)

Study information

Scientific Title

Earlier PEG placement in ALS patients with dysphagia: effects on survival, nutritional and functional status, and quality of life

Study objectives

Early Percutaneous Endoscopic Gastrostomy (PEG) placement in Amyotrophic Lateral Sclerosis (ALS) patients with dysphagia is associated with longer survival, better nutritional and functional status, and better quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethical Committee of Academic Medical Centre on the 19th March 2003 (ref: MEC 02/184).

Study design

Randomised, active-controlled, parallel group, multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Amyotrophic Lateral Sclerosis (ALS), Dysphagia

Interventions

Arm one: patients receive a PEG within one month after inclusion

Arm two: patients wait until either VC falls below 55%, or Hillel score is four or five, 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 in 15 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Survival.

Key secondary outcome(s)

1. Vital capacity
2. Body Mass Index (BMI)
3. Triceps skinfold
4. ALS Functional Rating Scale (ALSFRS)
5. Visual Analogue Scale for Quality of Life (VAS QoL)
6. Short Form health survey (SF 36)

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Patients with possible, probable, probable laboratory supported, or definite ALS
2. Dysphagia Hillel score seven or eight (ALS Severity Scale [ALSSS] dysphagia subscale)
3. Vital Capacity (VC) more than 65%
4. Aged more than 18 years and less than 85 years
5. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

1. Contra-indications for PEG

Date of first enrolment

04/08/2004

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Research organisation

Funder Name

Prinses Beatrix Fonds (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration