ISRCTN63827964 https://doi.org/10.1186/ISRCTN63827964

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 [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 08/02/2007	**Overall study status** Completed	
Last Edited 20/08/2021	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 untill 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 measure
Survival.

Secondary outcome measures
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)

Overall study start date
04/08/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
20

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)

Sponsor details
Department of Neurology
P.O. Box 22660
Amsterdam
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/#http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
Prinses Beatrix Fonds (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration