

Evaluation of gastrointestinal tolerance of a new thickening powder in patients with dysphagia

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/07/2009	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym

EVATT

Study objectives

H0: new thickening powder is equal to current thickening powder (regarding gastrointestinal tolerance).

H1: new thickening powder is unequal to current thickening powder (regarding gastrointestinal tolerance).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Randomised, double blind, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Dysphagia

Interventions

After a 3-day run-in period with current thickening powder patients will receive thickening powder A or B for 14 days.

Measurements of stool frequency and consistency, GI symptoms and food and fluid intake during the study period using food charts, stool charts and GI questionnaires.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Gastrointestinal symptoms (measurements: stool frequency and consistency, GI symptoms and food and fluid intake).

Secondary outcome measures

1. Patient product acceptability (intake thickening powder)
2. Carer product evaluation (product evaluation questionnaire)

Overall study start date

01/12/2005

Completion date

31/07/2006

Eligibility

Key inclusion criteria

1. Oropharyngeal dysphagia confirmed by the SLT using bed-side swallowing evaluation or videofluoroscopy
2. Neurogenic aetiology or caused by muscle weakness
3. Stable severity (require thickend drinks for at least 3 weeks after inclusion)
4. Written informed consent

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

50

Key exclusion criteria

1. Impaired consciousness level
2. Inadequate cognitive skills to comprehend study requirements and to communicate responses to questions
3. Bowel habit unable to be defined using the study specific gastrointestinal (GI) questionnaire
4. Enteral tube feeding corresponding to >50% of total energy intake
5. Use of any foods or fluids thickened with another commercial thickener

Date of first enrolment

01/12/2005

Date of final enrolment

31/07/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Numico Research B.V.

Wageningen

Netherlands

6700 CA

Sponsor information

Organisation

Numico Research BV (Netherlands)

Sponsor details

P.O. Box 7005

Wageningen

Netherlands

6700 CA

Sponsor type

Industry

ROR

<https://ror.org/00aj77a24>

Funder(s)

Funder type

Industry

Funder Name

Numico Research BV (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