

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

Submission date 14/02/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/02/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/07/2009	Condition category Signs and Symptoms	☐ 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

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

Primary study design

Interventional

Study design

Randomised, double blind, active controlled, parallel group trial

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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)

ROR

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

Funder(s)**Funder type**

Industry

Funder Name

Numico Research BV (Netherlands)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration