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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 14/02/2006	**Overall study status** Completed	
Last Edited 06/07/2009	**Condition category** Signs and Symptoms	

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