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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26061

Source
Nationaal Trial Register

Brief title
EVATT

Health condition

Dysphagia.

Sponsors and support

Primary sponsor: Numico Research B.V.
Bosrandweg 20
P.O. Box 7005
6700 CA Wageningen
The Netherlands
Tel. +31 (0)317-467800
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Patient product acceptibility (intake thickening powder);

2. Carer product evaluation (product evaluation questionnaire).

Study description

Background summary

Study to describe the gastrointestinal symptoms on a new thickening powder in amounts likely to be consumed by patients with dysphagia.

Study objective

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).

Study design

N/A

Intervention

After a 3-days run-in period with current thickening powder patients will receive thickening powder A or B for 14 days.
Measurements of stool frequency & consistency, GI symptoms and food & fluid intake during the study period using food charts, stool charts and GI questionnaires.

Contacts

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Eligibility criteria

Inclusion criteria

Main 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.

Exclusion criteria

Main 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 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2005
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	04-01-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL513
NTR-old	NTR555
Other	: N/A
ISRCTN	ISRCTN86521801

Study results

Summary results
Abstract geaccepteerd voor ESPEN 2007.