Effect of gum-based bolus viscosities on the safety of swallowing in patients with chronic post-stroke oropharyngeal dysphagia

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25638

Source
NTR

Brief title
TripleS

Health condition

Dysphagia

Sponsors and support

Primary sponsor: Nutricia Research BV
Source(s) of monetary or material Support: Nutricia Research BV

Intervention

Outcome measures

Primary outcome

Percentage of subjects that swallow viscosity levels 1, 2 and 3 safely (PAS score 1,2)

compared to thin iodine liquid control

Secondary outcome

• Safety of swallowing per individual viscosity as measured by:

• Percentage of subjects that swallow safely (PAS score 1,2)

• Percentage of subjects with penetration (PAS score 3,4,5)

• Percentage of subjects with aspiration (PAS score 6,7,8)

• Mean PAS score

• Efficacy of swallowing per individual viscosity as expressed by:

• Presence and severity of oral residue (score 0,1,2) Presence and severity of pharyngeal residue (score 0,1,2)

Study description

Background summary

This reference controlled, multiple dose, fixed order, single-blind and single-centre study is designed to evaluate whether addition of a gum based thickener increases safe swallowing compared to thin liquid in patients with chronic post-stroke oropharyngeal dysphagia.

Study objective

H0: The effect of at least one of the gum-thickened viscosities is equal to the effect using thin liquid, with respect to the safety of swallowing in patients with chronic post stroke oropharyngeal dysphagia.

H1: The effect of using gum-thickened viscosity level 3 is unequal to the effect of using thin liquid and the effect of using gum-thickened viscosity level 2 is unequal to the effect of using thin liquid and the effect of using gum-thickened viscosity of levels 1 is unequal to the effect of using thin liquid with respect to the safety of swallowing in patients with chronic post stroke oropharyngeal dysphagia

Study design

V0 (screening); V1 (Testday), Follow-up call

Intervention

Duration of intervention: 1-10 days
Intervention: thin iodine liquid as control versus iodine liquid thickened with a gum based thickener to different viscosity levels. Each variety will be given as a bolus in duplicate.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis of stroke, and minimum 28 days since stroke

2. Clinical signs or symptoms of swallowing dysfunction, based on Eating Assessment Tool (EAT-10) questionnaire, or bedside clinical test or water swallow test, or referral by medical doctor for Video FluoroScopy (VFS)-test, or current use of thickened products

3. No alterations in consciousness (score of 0 or 1 in the first question of NIH Stroke Scale (NIHSS))

4. Age ≥ 18y

5. Written informed consent

Exclusion criteria

1. Patients with respiratory insufficiency in need of additional oxygen

2. Dysphagia not related to stroke

3. History of progressive neurological disorders (e.g. Parkinson’s disease, MS)

4. Tumour or radiotherapy of the head and neck region

5. Unstable medical conditions that may interfere with VFS

6. Patients with swallowing dysfunction caused by xerostomia induced by drugs

7. Prior medical history or conditions (like tracheostomy tube) that would put the patient at risk of pre-existing swallow disorder

8. Severe cognitive disorders or Investigator's uncertainty about the willingness or ability of the patient to comply with the protocol requirements and instructions

9. Not able to undergo VFS due to incapability of sitting posture

10. Known pregnancy and/or lactating

11. Participation in any other studies involving investigational or marketed products within four weeks prior to start of the study

12. Allergy to any ingredient of test product or iodine products

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2016
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-01-2016
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	NL5363
NTR-old	NTR5628
Other	: DYS.2.C/B (Nutricia Research)

Study results

Summary results

n/a