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The Big Sip - Can we improve thickened fluids for people with swallowing problems

Submission date	Recruitment status	[_] Prospectively registered
13/12/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/12/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/08/2023	Signs and Symptoms	

Plain English summary of protocol

Background and study aims
The use of thickeners to thicken drinks and fluids in the routine care of patients with swallowing difficulties is a well-known practice that helps patients maintain hydration orally. Over the last decade, xanthan gum thickeners have grown in use as an alternative to starch-based thickeners. Precise ThickN INSTANT (PTI) is a novel product that delivers xanthan gum in a liquid form instead of a powder. The primary research objective of this study is to evaluate gastrointestinal tolerance, compliance, and preferences of participants with oropharyngeal dysphagia (OD) who are currently using a powder-based thickener when switched to PTI. The secondary research objectives of this study are to evaluate the acceptability of a new liquid thickener compared with the standard powder-based thickener that is the predominant product in use in England in the treatment of people with swallowing difficulties. This study aims to provide the required gastrointestinal tolerance, acceptability, compliance, and preference data for the Advisory Committee on Borderline Substances (ACBS).

Who can participate?
Adults who have been prescribed thickened fluids for clinical management

What does the study involve?
The study involves the oral administration of a liquid thickener food supplement and the subsequent evaluation of gastrointestinal tolerance and palatability of the thickener. Moreover, compliance and ease of use of the liquid thickener treatment as compared to the current mode of care (powdered thickener) will be evaluated.

What are the possible benefits and risks of participating?
The benefits of participating are that participants will be exposed to a new thickener which may be more palatable and offer more appealing thickened beverage options resulting in greater oral hydration compliance. Risks to participating are adverse reactions such as bloating, distention, diarrhea and or intolerance to the treatment thickening option.

Where is the study run from?
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2021 to June 2023

Who is funding the study?
Precise Health, a division of Trisco Foods Pty Ltd (Australia)

Who is the main contact?
Sarah Birchall, sarah.birchall4@nhs.net (UK)

Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
314590

Central Portfolio Management System (CPMS)
52295

Protocol serial number
STH22185

Study information

Scientific Title
The Big Sip. Can we improve thickened fluids for people with swallowing problems: an investigation into the gastrointestinal tolerance, acceptability, compliance and patient preference to Precise ThickN INSTANT thickener

Acronym
The Big Sip

Study objectives
Evaluation of gastrointestinal tolerance and palatability of liquid thickener in the clinical management of oropharyngeal dysphagia patients for whom thickened fluids have been prescribed

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 13/09/2022, London - Camberwell St Giles Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44(0)2071048138; camberwellstgiles.rec@hra.nhs.uk), ref: 22/LO/0471

Primary study design
Interventional

Study design
Prospective single-arm intervention trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Dysphagia

Interventions
After enrollment into the study, participants remain on their usual mode of care (current powdered thickener for 7 days). During this time, the subject and/or their carer(s) will record tolerance and compliance data in the study diaries. The palatability of the participants' current powdered thickener will be evaluated with a 6-question survey using an end-anchored 10-point hedonic scale. Enrolled participants will be switched from their current thickener to having all their beverages thickened with the treatment (liquid thickener). There will be a 5-day washout period to clear the gastrointestinal (GI) tract and ensure any GI issues are related to the specific treatment. During this time, the subject and/or their carer(s) will continue to record tolerance and compliance data in the study diaries. For the subsequent 14 days, enrolled participants will be served all their liquids thickened with the treatment. During this phase, daily questionnaires will be kept that continue to monitor all the indicators of gastrointestinal tolerance and compliance. On the last day of the intervention, the palatability of the treatment will be assessed with the same questionnaire used to assess the palatability of the participants' baseline thickener during the phase I baseline period.

Intervention Type
Supplement

Primary outcome(s)
1. Gastrointestinal tolerance of the liquid thickener measured using a non-validated gastrointestinal symptoms questionnaire daily for 14 days
2. Palatability of the liquid thickener measured using a non-validated palatability questionnaire on the last day of the intervention on day 14

Key secondary outcome(s)
Compliance and ease of use of liquid thickener as compared to the current mode of care (powdered thickener) measured using a non-validated fluid intake questionnaire daily

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Aged 18 years old and above
2. Already taking adequate amounts of thickened fluids as determined by the Speech and Language Therapist
3. Currently using a xanthan gum-based thickener that has been Advisory Committee on Borderline Substances (ACBS) approved
4. Expected to require thickened fluids for at least 4 more weeks from the point of recruitment
5. Already using xanthan gum thickener at a prescribed identified IDDSI level with no reported gastrointestinal difficulties
6. Able to give written consent or witnessed verbal consent if unable to write
7. Mild acquired communication difficulties who understand 3+ information-carrying words as determined by the Consent Support Tool CST
8. Participants with the cognitive ability to engage meaningfully in conversation and who can access and retain the study information and consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
29

Key exclusion criteria
1. Not requiring thickened fluids. Specifically, who have not been prescribed thickened fluids by a qualified health practitioner after an oropharyngeal dysphagia diagnosis for acute or chronic swallowing difficulties
2. Requiring enteral tube feeding or parenteral nutrition, including patients who require top-up enteral feeding alongside the oral intake
3. Medical or dietary contraindications to any of the ingredients of PTI
4. The high (>85%) fibre content in xanthan gum may cause gastrointestinal difficulties. Therefore, participants that are currently using starch-based thickeners that do not contain fibre will be excluded
5. To avoid potentially adverse effects, participants with inflammatory bowel disease or previous bowel resection will be excluded due to the high (greater than 85%) fibre content of xanthan gum which can cause gastrointestinal irritation
6. Enrolled in any other studies concomitantly or within a month prior to entry into this study
7. The investigator has concerns regarding the ability or willingness of the patient and/or care provider to comply with protocol requirements
8. Currently using a pre-thickened beverage or have used PTI already
9. Using a powdered thickener that is not Advisory Committee on Borderline Substances (ACBS)

approved
10. Significant cognitive difficulties
11. Acquired communication difficulty will be excluded if they present with significant visual and /or hearing difficulties, and have less than 3 keyword understanding, as these difficulties will have an impact on the completion of the survey

Date of first enrolment
25/11/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Hallamshire Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Glossop Road
Sheffield
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Study participating centre
York Hospital
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YO31 8HE

Sponsor information

Organisation
Trisco Foods Pty Ltd

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The sponsor will not be sharing participant-level data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other unpublished results			04/08/2023	No	No