GEBS - A screening tool for swallowing disorders in geriatric patients

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered[X] Protocol		
23/03/2021				
Registration date	Overall study status Completed	Statistical analysis plan		
24/03/2021		[X] Results		
Last Edited	Condition category	Individual participant data		
23/10/2025	Signs and Symptoms			

Plain English summary of protocol

Background and study aims

Ageing causes changes in the swallowing process. More time is needed to chew, transport and prepare the food for swallowing inside the mouth and to actually swallow. This process can be disordered, known as dysphagia. Dysphagia can cause complications such as too little intake of food and water but also lead to an inflammation of the lung tissue when food or drinks enter the airways and coughing can not expel it completely. Diseases that are linked with dysphagia are Stroke, Morbus Parkinson and cognitive diseases - all those are more common in older people. It is therefore important to detect people with swallowing disorders early in order to treat the swallowing process, making it safe to eat and drink again. There are no published screening tools that have been developed for older people, making it hard to correctly diagnose those in need of further investigation and treatment. This study aims to close this gap by providing a safe, short and easy screening tool for the detection of swallowing disorders in people aged 75 years and older.

Who can participate?

People admitted at one of the two study sites within the time of recruitment aged 75 years and older who have no history of head and neck cancers or severe stroke, who have a regular breathing mechanism (no tracheostoma, meaning not breathing through their neck) and who don't suffer from advanced dementia.

What does the study involve?

By participating patients agree to have the new test (GEBS) administered to them, this includes a few questions followed by a few sips of water alternating with saying "AH" in a loud voice as well as eating a small bowl of pureed food. Within a week of that initial test, they will then have an instrumental swallowing examination, where a small endoscope with a camera is passed through the nose into the back of the mouth. Once this is in place participants will be asked to swallow liquid, pureed and solid foods which have been colored with non-toxic food colouring.

What are the possible benefits and risks of participating?

The possible benefits are a thorough documentation of the swallowing process at the present time, which is a valuable baseline even for healthy people. In case there is dysphagia detected because of study participation, patients will benefit from early treatment. Risks are very low,

mainly discomfort and possible nose bleed during the endoscopic evaluation of swallowing. A few cases of decreased blood pressure or changes in heart rhythm have been reported, but none of those required any medical assistance.

Where is the study run from?

The study is run as the dissertation project of the main researcher at the Paracelsus Medical University Salzburg (Austria)

When is the study starting and how long is it expected to run for? April 2019 to September 2024

Who is funding the study? Investigator initiated and funded

Who is the main contact?
Susanne M. Javorszky, susanne.javorszky@stud.pmu.ac.at

Contact information

Type(s)

Public

Contact name

Mrs Susanne Maria Javorszky

ORCID ID

https://orcid.org/0000-0003-4219-5857

Contact details

Institut für Pflegewissenschaft und -praxis Strubergasse 21 Salzburg Austria 5020 +43 69981936162 susanne.javorszky@stud.pmu.ac.at

Type(s)

Scientific

Contact name

Mrs Susanne Maria Javorszky

Contact details

Institut für Pflegewissenschaft und -praxis Strubergasse 21 Salzburg Austria 5020 +43 69981936162 susanne.javorszky@stud.pmu.ac.at

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

201901

Study information

Scientific Title

Validation of the Geriatric Bedside Swallow Screen

Acronym

GEBS

Study objectives

The screening tool GEBS is sensitive to the presence of dysphagia

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Approved 07/03/2022, Ethics board of the city of Vienna (Ethikkommission der Stadt Wien, 1030 Wien, Thomas-Klestil-Platz 8/1, Austria; +43 1 4000 87754; ethikkommission@m15. magwien.gv.at), ref: EK-21-212-1021
- 2. Approved 14/06/2022, Ethikkommission für das Bundesland Salzburg (Sebastian-Stief-Gasse 2, 5020 Salzburg; +43 662 8042-2375; ethikkommission@salzburg.gv.at), ref: 1040/2022

Study design

Observational cohort study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Early detection of dysphagia in geriatric patients

Interventions

Observational trial using a comparison between the index test (GEBS) and an internationally standardised and well documented, reliable instrumental swallowing test (FEES) to calculate the sensitivity and specificity of the index test

Index test, GEBS, is applied (anamnesis plus observation of liquid and bolus intake with structured documentation). Within 6 days FEES (flexible endoscopic evaluation of swallowing endoscope is lead through the nose so the larynx can be observed while swallowing different types of boli) is applied for objective diagnosis of dysphagia (and severity, if dysphagia is diagnosed).

Intervention Type

Other

Primary outcome(s)

Presence/absence of dysphagia measured using:

- 1. Index Test GEBS will be measured as PASS/FAIL at the beginning of participation
- 2. FEES using the Penetration-Aspiration Scale (PAS) within one week of the GEBS

Key secondary outcome(s))

Inter-Rater Reliability will be measured by applying the GEBS twice within three days by two different observers

Completion date

30/09/2024

Eligibility

Key inclusion criteria

- 1. Aged 75 years or older
- 2. Admitted at one of the two study sites at the time of data collection
- 3. Able to give informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

75 years

Sex

All

Total final enrolment

30

Key exclusion criteria

- 1. Tracheostoma
- 2. Cognitive desease (Diagnosis of dementia) with MMSE 20 or lower
- 3. Anamnesis of stroke with NIHSS of 20 or higher

4. Anamnesis of neck-throat-cancer with structural changes in the anatomy relevant for swallowing

Date of first enrolment 01/07/2022

Date of final enrolment 31/07/2024

Locations

Countries of recruitment

Austria

Study participating centre
Universitätsklinik für Geriatrie
Christian-Doppler-Klinik
Ignaz-Harrer-Straße 79
Salzburg
Austria
5020

Study participating centre
Haus der Barmherzigkeit Seeböckgasse
Seeböckgasse 30a
Wien
Austria
1160

Sponsor information

Organisation

Paracelsus Medical University

ROR

https://ror.org/03z3mg085

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/07/2025	23/10/2025	Yes	No
<u>Protocol article</u>		11/08/2023	14/08/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Protocol file</u>			06/04/2021	No	No