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GEBS - A screening tool for swallowing disorders in geriatric patients

Submission date 23/03/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/03/2021	**Overall study status** Completed	
Last Edited 19/07/2024	**Condition category** 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet (in German)

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 measure
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

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

Overall study start date
10/04/2019

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

Age group
Senior

Lower age limit

75 Years

Sex
Both

Target number of participants
100

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
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Sponsor information

Organisation
Paracelsus Medical University

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Sponsor type
University/education

Website
http://www.pmu.ac.at/

ROR
https://ror.org/03z3mg085

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication of study protocol followed by publication of results in a high-impact peer-reviewed journal.

Intention to publish date
01/03/2025

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?
Protocol file			06/04/2021	No	No
Protocol article		11/08/2023	14/08/2023	Yes	No