Trial Description

Title

Oropharyngeal dysfunction in patients with systemic sclerosis: frequency and therapeutic effects of speech therapy

Trial Acronym

LogoSS

URL of the trial

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Brief Summary in Lay Language

Up to 98% of patients with systemic sclerosis (SSc) Show Involvement of the gastrointestinal System. Up to 78% of patients with SSc report coughing and/or a sore voice. In this study we want to evaluate the frequency of oropharyngeal dysfunction, like oropharyngeal dysphagia or impairment in speaking/articulation, in patients with SSc. Secondly we want to evaluate the effect of speech therapy on these impairments.

Brief Summary in Scientific Language

Up to 98% of patients with systemic sclerosis (SSc) show involvement of the gastrointestinal system (GI) [1]. While meteorism, heartburn and GI dysmotility are very common and accessible to pharmacologic treatment on an evidence based level [1–3], checking for oropharyngeal dysfunction is usually not part of the standard diagnostic algorithm. However, in a survey of the German Network for Systemic Sclerosis (DNSS) patients reported coughing and/or a sore voice in up to 78% [1]. As impairment in speaking or swallowing for example does not only substantially reduce quality of life, it can also be very stigmatizing. In addition, the usual prokinetic therapy of GI-involvement, e.g. metoclopramide, does not appear to improve these symptoms. As the first step to approach this problem is the qualitative and quantitative description, we want to evaluate the oropharyngeal function in our cohort of SSc patients by detailed logopedic assessment.Secondly, effects of speech therapy shall be evaluated for treating oropharyngeal dysfunction in SSc.

[1] Schmeiser T, Saar P, Jin D, Noethe M, Müller A, Soydan N, et al. Profile of gastrointestinal involvement in patients with systemic sclerosis. Rheumatol Int 2012;32:2471–8. doi:10.1007/s00296-011-1988-6.
[2] Boeckxstaens GE, Bartelsman JFWM, Lauwers L, Tytgat GNJ. Treatment of GI dysmotility in scleroderma with the new enterokinetic agent prucalopride. Am J Gastroenterol 2002;97:194–7. doi:10.1016/S0002-9270(01)03958-2.
[3] Mercado U, Arroyo de Anda R, Avendaño L, Araiza-Casillas R, AvendañoReyes M. Metoclopramide response in patients with early diffuse systemic sclerosis. Effects on esophageal motility abnormalities. Clin Exp Rheumatol 2005;23:685–8.

Do you plan to share individual participant data with other researchers?

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No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00020776**
- Date of Registration in DRKS: **2020/03/16**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **181/19 , Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig-Universität Gießen**

Secondary IDs

Health condition or Problem studied

- ICD10: **M34.0 - Progressive systemic sclerosis**

Interventions/Observational Groups

- Arm 1: **Patiens with systemic sclerosis**

  At start oropharyngeal dysfunction will be assessed subjectively by the patient as well as objectively by a speech therapist. Oropharyngeal dysfunction comprises: oropharyngeal dysphagia (impairment of oropharyngeal swallowing), Reflux, impairment of voice, impairment in speaking/articulation, impairment in breathing (oropharyngeal breathing), impairment of oropharyngeal muscle function (tongue, palate, mimic muscles). A patient is positive for oropharyngeal dysfunction when he meets 1 of the criteria.

  This study will evaluate the frequency of oropharyngeal dysfuntion in patients with SSc as well as short-term responce to logopedic treatment after 7 days and Long-term effects (after 3 months of treatment).

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Screening**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

1) Frequency of oropharyngeal dysfunction (at least 1 positive criteria) in patients with systemic sclerosis

Oropharyngeal dysfunction comprises: oropharyngeal dysphagia (impairment of oropharyngeal swallowing), Reflux, impairment of voice, impairment in speaking/articulation, impairment in breathing (oropharyngeal breathing), impairment of oropharyngeal muscle function (tongue, palate, mimic muscles).

Patients will assess (subjective): oropharyngeal dysphagia (impairment of oropharyngeal swallowing), Reflux, Impairment of voice, impairment in speaking/articulation.

A speech therapist will assess (objective): oropharyngeal dysphagia (impairment of oropharyngeal swallowing), impairment of voice, impairment in speaking/articulation, impairment in breathing (oropharyngeal breathing), impairment of oropharyngeal muscle function (tongue, palate, mimic muscles).

Secondary Outcome

1. subjective improvement of oropharyngeal dysfunction in up to 7 days after initial speech therapy (2 appointments: Evaluation and therapy) assessed on a visual analogue scale (VAS) from 0 to 100 mm
2. subjective improvement of oropharyngeal dysfunction after 3 months of logopedic treatment assessed on a visual analogue scale (VAS) from 0 to 100 mm
3. objective improvement (logopedic reevaluation) of oropharyngeal dysfunction after 3 months of logopedic treatment (no improvement - little improvement - good improvement)
4. change in logopedic evaluation after 3 months of therapy using the Hoffmann-SSc-Scale
5. Change in bodyweight
6. Change in SHAQ, FFbH and HAQ
7. Change in daily doses and frequency of procinetic pharmacotherapy
8. Change in Hb, MCV, MCH and transferrinsaturation

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Abt. Rheumatologie, Immunologie, Osteologie und Physikalische Medizin, Campus Kerckhoff der Justus-Liebig-Universität Gießen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/03/01**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

- 18 - 99 years of age
- systemic sclerosis (both limited and diffuse cutaneous systemic sclerosis) Meeting the ACR/EULAR classification criteria 2013
- Written informed consent obtained from the subject or his/her legally acceptable representative
- Understanding of study procedures and willingness to abide by all procedures during the course of the study.

Exclusion criteria

- cognitive impairment
- stroke (in the last 6 months)
- aphasia
- dementia, epilepsy or any other neurologic condition in which speech therapy cannot be administered
- Myositis
- dysphagia not due to systemic sclerosis
- Ulcera / injury of the mouth or oropharynx
- ventilation

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethik Votum Logoss Giessen**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*