

Capsaicin for post stroke dysphagia (CADYS)

Principal Investigator:	PD. Dr. med. Georg Kägi
Status:	planned
Project Start:	2019
Project End:	approx.2021
Trial Design/Class:	multicenter, randomized, double blind, placebo controlled, Class C-Clinical Trial
Number of Patients:	82
Centers:	3 (St. Gallen, Basel, Aarau)
Sponsor/Partner:	Kantonsspital St. Gallen/ PD. Dr. med. Georg Kägi
Funding:	CTU KSSG, Swiss Heart Association, Deutschschweizer Logopädenverband

Summary:

Dysphagia as a result of ischemic cerebral infarction is receiving little attention in current clinical research, although it represents a limiting complication to the daily lives of patients with adverse effects on long-term patient outcomes.

To date, no drug therapy for dysphagia is sufficiently established.

Capsaicin is known to have stimulatory effects on nociceptive and sensory afferent tracts and has shown, in some small studies, an effect on unspecified swallowing disorders in older people. Swallowing is a complex act which needs amongst others sensory input, which can be insufficient after stroke. Hypothetically, capsaicin can have positive effects on post stroke dysphagia most probably via sensory-afferent stimulation.

Objectives:

The aim is demonstrate the positive effects of capsaicin therapy over placebo in patients with dysphagia in the acute stage of stroke. The efficacy is measured by clinical functional parameters (Functional Oral Intake Scale-FOIS) as well as para-clinically with the Penetration/Aspiration Scale obtained by Flexible Endoscopic Evaluation of Swallowing (FEES). After inclusion, patients are randomized 1: 1 to placebo or capsaicin 1.5 mg which is taken 3 times a day at the beginning of meals or applied manually by staff for patients with enteral feeding during swallowing assessments. Therapy is given for 7 days, followed by a new swallowing evaluation using FEES and PAS. Patients with persistent dysphagia will continue therapy for 30 days and will be evaluated with FOIS at the end of treatment.

In addition, the effect of capsaicin therapy on the dysphagia-associated complications, such as aspiration pneumonia or neediness as well as the subjective dysphagia-associated quality of life (Swal-QoL) will be assessed.