Trial Description

Title

Prospective randomized controlled study on the influence of closed vs open tracheostomy tubes on swallowing in patients with neurogenic dysphagia

Trial Acronym

manometry/ cap

URL of the trial

[---]*

Brief Summary in Lay Language

Tracheotomized patients usually breathe via the trachoesotmy tube and not via nose and mouth. Various studies showed that an occlusion of the tube (and thereby forcing the patient to breathe via nose and mouth) improves pharyngeal and laryngeal clearing. However, it remains unclear whether the occlusion can also better aspiration and the patients´ ability to swallow. This study is performed to optimize treatment of tracheotomized patients and to clarify whether dysphagia therapy should be preferably done with open or closed tracheostomy tubes.

Brief Summary in Scientific Language

It is unclear whether swallowing therapy in tracheotomozed patients should be done with open or closed tracheostomy tubes. There are conflicting results concerning the impacts of closed tubes on aspiration and swallowing physiology. The purpose of this instrumental study (flexible endoscopic evaluation of swalowing, pharyngeal manometry) is to compare aspiration and pharyngeal physiology in patients with open (respiration via the tube) or closed (respiration via nose and mouth) tracheostomy tubes.
The study will be performed in 40 tracheotomized patients suffering from neurogenic dysphagia.

Organizational Data

- DRKS-ID: **DRKS00003060**
- Date of Registration in DRKS: **2011/05/13**
- 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.: **10064 , Ethik-Kommission der Bayerischen Landesärztekammer**

Secondary IDs

Health condition or Problem studied

- ICD10: **R13.0 - [generalization R13: Dysphagia]**
- ICD10: **[---]* - [---]***

Interventions/Observational Groups

- Arm 1: **20 tracheotomized patients suffering from dysphagia after a single monohemispheric lesion. 1st phase: respiration via nose/ mouth; 2nd phase: respiration via tracheostomy tube**
- Arm 2: **20 tracheotomized patients suffering from dysphagia after a single monohemispheric lesion. 1st phase: respiration via tracheostomy tube; 2nd phase: respiration via nose/ mouth**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Manometric pressure differences (between base of tongue and pharyngeal wall) during swallowing
method: pharyngeal manometry
measurement points: oropharynx, hypopharynx, upper esophageal sphincter
data points: maximal pressure, duration of pressure

Secondary Outcome

degrees of aspiration (Penetration-Aspiration Scale, Rosenbek et al., 1996); data extraction: simultaneous manometric and endoscopic measurement during swallowing (puree)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/05/16**
- 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: **no maximum age**

Additional Inclusion Criteria

- neurogenic dysphagia [clinical signs: modified Evan´s Blue Dye test (Belafsky et al., 2003); De-Pippo-water test (Suiter & Leder, 2008)]
- monohemispheric lesions
- patients will be included consecutively
- no previous neurologic or relevant anatomic morphologic lesions
- no peripheral (2nm MN) vocal cord paralysis
- effective reflectory cough
- trach tube can be uncuffed for 10 minutes without relevant SPO2 decrease
- no oropharyngeal tumors
-no previous surgery (aero-digestive tract)

Exclusion criteria

- no written consent
- severe not substitutable coagulation deficits
- esophageal diverticulum
- respiratory insufficiency (SaO2<90%)

- bradycardia (<50/min)

Addresses

■ **Primary Sponsor**

Schoen Klinik Bad Ailbing
Kolbermoorer Straße 72
83043 Bad Aibling
Germany

Telephone: **08061-903-0**
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Schoen Klinik Bad Ailbing
Mr. Dr. Peter Bader
Kolbermoorer Straße 72
83043 Bad Aibling
Germany

Telephone: **08061-903-0**
Fax: **[---]***
E-mail: **pbader at schoen-kliniken.de**
URL: **http://www.schoen-kliniken.de/aib**

■ **Contact for Public Queries**

Schoen Klinik Bad Aibling
Mr. Christian Ledl
Kolbermoorer Str. 72
83043 Bad Aibling
Germany

Telephone: **+49 (0) 8061 903 1583**
Fax: **[---]***
E-mail: **cledl at schoen-kliniken.de**
URL: **http://www.schoen-kliniken.de/aib**

Sources of Monetary or Material Support

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

Schoen Klinik Bad Aibling
Kolbermoorer Str. 72

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Schoen Klinik Bad Aibling
Kolbermoorer Str. 72
83043 Bad Aibling
Germany

Telephone: **+49 (0) 8061 903 0**
Fax: **[---]***
E-mail: **bschaepers at schoen-kliniken.de**
URL: **[---]***

Status

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

Trial Publications, Results and other documents

** 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.*