

Trial Description

Title

Long-term results after surgical treatment of diffuse idiopathic skeletal hyperostosis (DISH) causing dysphagia

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Diffuse idiopathic skeletal thyroidosis (DISH), also known as the Morbus Forestier, is a non-inflammatory, systemic skeletal disease. This results in an ossification of tendon attachment sites. Above all, the spine is affected. There is a bony bridging of the intervertebral discs. As a result, pronounced bone pores (osteophytes) are formed, which can impair the swallowing action in the region of the cervical spine. The resulting swallowing disorder (dysphagia) can be so pronounced that the osteophytes must be removed surgically. Since the disease pattern is rare, there is very little literature and, in particular, little long-term results with regard to surgical therapy.

The aim of this research project is the retrospective recording of the perioperative and postoperative course of treatment in surgical therapy of patients with dysphagia due to diffuse idiopathic skeletal hyperostosis as well as the collection of data on long - term prognoses by means of telephone interviews and questionnaires or in the case of current complaints with a clarification request from the patient in the Framework of an outpatient investigation.

Brief Summary in Scientific Language

In the case of unsuccessful conservative therapy of swallowing disorder, the operative removal of the space-demanding osteophytes is recommended by several authors as effective treatment (1 - 3). However, these are studies which, on the one hand, involve very few patients and, on the other hand, often only refer to the short-term postoperative course. Only individual studies are concerned with the long-term trend (4).

- 1. Goel R, Sampath P, Mikaelian DO. Dysphagia caused by cervical osteophytes: three cases treated by surgery. Otolaryngol Head Neck Surg 1999, 120: 92-6.**
- 2. Fuerderer S, Eysel-Gosepath K, Schroder U, et al. Retro-pharyngeal obstruction in association with osteophytes of the cervical spine. J Bone Joint Surg Br 2004, 86: 837-40.**
- 3. Kritzer RO, Parker WD. DISH: a cause of anterior cervical osteophyte-induced dysphagia. Spine 1988, 13: 130-2.**
- 4. Urrutia J, Bono CM. Long-term results of surgical treatment of dysphagia**

secondary to cervical diffuse idiopathic skeletal hyperostosis. Spine, J. 2009, (9): e13-7

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013049**
- Date of Registration in DRKS: **2017/09/19**
- 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.: **318/17** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **M48.10** - [generalization **M48.1**: Ankylosing hyperostosis [Forestier]]
- ICD10: **R13** - Dysphagia

Interventions/Observational Groups

- Arm 1: **Patients \geq 18 years with diffuse idiopathic skeletal hyperostosis who were treated surgically during the period from 2005 to 2015 due to dysphagia: Retrospective recording of the perioperative and postoperative course of treatment as well as the collection of data on long-term prognoses by means of telephone interviews and questionnaires or in the case of current complaints with a clarification request from the patient in the Framework of an outpatient investigation.**

Characteristics

- Study Type: **Non-interventional**

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

Primary Outcome

Retrospective survey of the short-term improvement of the dysphagia after surgery by medical records and survey of the long-term results via questionnaires / telephone interviews

Secondary Outcome

Retrospective survey of perioperative data (perioperative and postoperative complications, hoarseness, cervical discomfort, difficulty with breathing; etiology of diffuse idiopathic skeletal hyperostosis (diabetes, lipid disorder, exposure to fluorides, vitamins A, obesity, hypertension, hyperinsulina, hyperuricaemia) by medical records and survey of the long-term results (recurrence of hyperostoses in imaging, patient satisfaction, course of disease) by questionnaires / telephone interviews

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Neurochirurgie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/10/02**

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- Target Sample Size: **5**
- 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

Patients \geq 18 years with diffuse idiopathic skeletal thyroidosis who were treated surgically during the period from 2005 to 2015 due to dysphagia.

Exclusion criteria

Patients < 18 years

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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Sources of Monetary or Material Support

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

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Status

■ **Recruitment Status: Recruiting complete, follow-up complete**

■ **Study Closing (LPLV): 2018/01/01**

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Trial Publications, Results and other documents

- Abstract **Long-term results after surgical treatment of diffuse idiopathic skeletal hyperostosis (DISH) causing dysphagia.**

Please note:

There are additional attributes available concerning this trial. To open an extended view please [click here](#).