Trial Description

Title

Peroral Endoscopic Myotomy in Hypercontractile Esophageal motility disorders

Trial Acronym

POEM-HYPE

URL of the trial

[---]*

Brief Summary in Lay Language

Patients with symptomatic hypercontractile esophageal motility disorders may have chest pain, retrosternal pressure, dysphagia and/or regurgitation. Established treatment is often with limited effect (medication, balloon distension, botulinum toxin injection, laparocopic myotomy). Peroral endoscopic myotomy (POEM) of the esophageal circular muscle is an established therapy that could be also effective in hypercontractile esophageal motility disorders. This view is supported by studies indicating effectivness in achalasia (type III, Chicago classification) and case reports in hypercontractile esophageal motility disorders. However, systematic investigations are not available yet. In this prospective open study, patients with symptomatic hypercontractile esophageal motility disorders will be investigates systematically. The patients receive standardized questionaires about their symptoms and quality of life, upper GI endoscopy with esophageal biopsies, 24h-pH-metry-impedance measurement, gastrografin swallow and POEM. Treatment effectivity will be controlled by repeated questionairs and investigations 3 weeks after treatment and by repeated questionaires 6 an 12 month after treatment.

Brief Summary in Scientific Language

Prospective, open, non randomized clinical study with upper GI endoscopy, biopsy, gastrografin-swallow, high resolution manometry, esophageal 24h-pH-metry-impedance measurement and peroral endoscopic myotomy (POEM) in patients with achalasia type III and hypercontractile esophageal motility disorders (esophageal spasm, hypercontractile esophagus)

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00007793**
- Date of Registration in DRKS: **2015/02/11**
- 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.: **14-359 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **K22.0 - Achalasia of cardia**
- Free text: **Hypercontractile esophageal motility disorders**

Interventions/Observational Groups

- Arm 1: **All consecutive patients with symptomatic achalasia type III and hypercontractile esophageal motility disorders (Chicago classification) receive standardized questionaires, upper GI endoscopy, biopsy, gastrografin-swallow, high resolution manometry, esophageal 24h-pH-metry-impedance measurement and peroral endoscopic myotomy (POEM)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- 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**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

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

Reduction of symptoms of at least 90%, Eckardt score < 3. Symptom reduction is measured by standardized questionaires (SF-36, Eckardt score, visuell-analogue scales) 3 weeks, 6 and 12 month after POEM.

Secondary Outcome

Reduction of hypercontractile esophageal motility disordera, DCI < 5000 mmHg-s-cm,
< 20% preliminary contractions, reduced DL < 4,5 Sekunden
Achalasia Typ III: IRP4 < 10 mmHg or resting pressure lower esophageal sphincter < 5 mmHg

These Parameters will be measured by gastrografin swallow, high resolution esophageal manometry and 24h-pH-metry-impedance measurement 3 weeks after POEM.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Medizinische Klinik II, HELIOS Klinikum Krefeld, 47805 Krefeld**
- Medical Center **Klinik für Innere Medizin, Gastroenterologie, Hepatologie und Onkologie, Elisabeth-Krankenhaus, 45138 Essen**
- Medical Center **Medizinischen Klinik, Krankenhaus Köln-Holweide, Neufelder Str. 32, 51067 Köln**

- University Medical Center **Klinik für Gastroenterologie und Hepatologie, Uniklinik Köln , Kerpener Str. 62, 50924 Köln**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/03/01**
- Target Sample Size: **70**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

All consecutive recruited achalsia typ III and symptomatic hypercontractile esophageal motility disorders (Chicago Classifikation) vor
Eckardt Score > 3
18 – 80 years
ASA class 1 and 2

Exclusion criteria

Patients < 18 years
Patients without consent
Patients with coagulation disturbances (Quick<50%, Thromboytes < 50.000/ul)
pregnancy
previous surgery esophagus and/or stomach
Liver cirrhosis with/without esophageal varices
Eosinophilic esophagitis
Barretts esophagus
Esophageal strictures
Premalignant and/or malignant Esophageal disorders
Extremly dilated esophagus (> 6cm)
Achalasia Type I und II (Chicago Classifikation)

Addresses

- **Primary Sponsor**

  Medizinische Klinik II, HELIOS Klinikum Krefeld
  Mr. Prof. Dr. med. Thomas Frieling
  Lutherplatz 40

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Sources of Monetary or Material Support

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

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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.*