Trial Description

Title

The osteopathic treatment of patients with gastroesophageal reflux disease (GERD). A randomized controlled trial

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Gastroesophageal reflux disease (GERD), characterized by troublesome heartburn and/or acid regurgitation, is a chronic disease that has a substantial impact on health-related quality of life. It is the most common gastrointestinal diagnosis recorded during visits to outpatient clinics. In this study, the effectiveness of osteopathic treatments in patients suffering from gastroesophageal reflux should be investigated. The treatment group receives four osteopathic treatments in addition to standard drug therapy, the control group treated only with medication. It will be addressed the question whether it is possible to reduce gastrointestinal symptoms.

Brief Summary in Scientific Language

The objective of this randomized controlled trial is to evaluate the effectiveness of osteopathic treatments in patients suffering from gastroesophageal reflux. For the primary outcome parameter the gastrointestinal symptoms are measured with the Reflux disease questionnaire RDQ. The two groups are allowed to maintain their standard medication ("usual care") for the reflux.

Organizational Data

- DRKS-ID: **DRKS00006824**
- Date of Registration in DRKS: **2014/09/30**
- 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.: **EKO02 , Ethikkommission für Osteopathie (EKO)**

Secondary IDs

Health condition or Problem studied

- ICD10: **K21 - Gastro-oesophageal reflux disease**

Interventions/Observational Groups

- Arm 1: **4 osteopathic treatments over a period of eight weeks + usual care (medication) during the whole study phase**
  Each osteopathic intervention lasts 40 – 60 minutes
- Arm 2: **usual care (medication)**

Characteristics

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

Primary Outcome

Gastrointestinal symptoms will be measured with the Reflux disease Questionnaire (RDQ) at the begin of the trial (baseline) and at the end of treatments (eight weeks after study begin)

Secondary Outcome

Quality of life, measured with the QORAD-questionnaire (Quality of Life in Reflux and Dyspepsia) at begin and end, use of medication (medication diary during the whole study), osteopathic dysfunctions (as quantitative listing)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Köln, Bielefeld. (Die Studie wird von drei Osteopathen in ihren Praxen durchgeführt. Sie haben die 5-jährige osteopathische Ausbildung, ca. 1350 Std. erfolgreich abgeschlossen und das abschließende klinische Examen bestanden)**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/10/01**
- 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: **75 Years**

Additional Inclusion Criteria

1.) Patients who suffer from gastroesophageal reflux symptoms, at least for a half year and at least 1-2 / week
2.) Endoscopy less than 1 year without pathological findings. Only patients with grade I according to Savary / Miller will be included.
3.) Reflux diagnosed by a physician

Exclusion criteria

Neoplasms, Barrett esophagus, reflux grade II, III, IV according to Savary/Miller, reflux during pregnancy, heart disease, esophageal varices, diabetic neuropathies, alcoholic neuropathy, surgery in the gastrointestinal tract in the last 6 months

Addresses

- **Primary Sponsor**

  Praxis für Osteopathie
  Mr. Andreas Lynen
  An der Wachsfabrik 3

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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): **2016/09/29**

Trial Publications, Results and other documents

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.