

Trial Description

Title

Health related quality of life after operative or conservative treatment of recurrent diverticular disease of the sigmoid colon: a monocentric cohort study

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Patients who were treated for chronic diverticular disease at the Schön Klinik Neustadt will be surveyed by questionnaire. The aim of this study is to examine the effect of the treatment on the patients' health related quality of life.

Brief Summary in Scientific Language

Diverticular disease is the inflammation of diverticula on the grounds of local obstruction caused by compressed faeces or indigestible food compounds and predisposing factors. In western industrialised nations, diverticular disease is common and its prevalence increases with age. Diverticula can be found in 70% of 80-year-olds but in only about 5% of 40-year-olds, those diverticula are mostly asymptomatic. In this study only patients with chronic-recurrent Diverticular disease will be included (equivalent to Hansen Stock Stadium III). Currently there is no German guideline for the treatment of diverticular disease. The guidelines of the Scientific Committee of the European Association for Endoscopic Surgery Task Force and the American Society of Colon and Rectal Surgeons suggest a surgical approach after the second episode of diverticular disease. Few Studies have been conducted aiming to investigate the effect of the treatment on the quality of life. Patients who have received treatment for chronic-recurrent diverticular disease as the major diagnosis between 01.01.2010 and 31.12.2011 at the Schön Klinik Neustadt will be included in this study. Primary aim of the study is the comparison of the health related quality of life after operative or conservative treatment in patients with chronic-recurrent diverticular disease

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006132**
- Date of Registration in DRKS: **2014/05/23**
- 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.: **13-165 , Ethik-Kommission Universität zu Lübeck Medizinische Fakultät des Universitätsklinikums Schleswig-Holstein**

Secondary IDs

Health condition or Problem studied

- ICD10: **K57.22 - [generalization K57.2: Diverticular disease of large intestine with perforation and abscess]**
- ICD10: **K57.23 - [generalization K57.2: Diverticular disease of large intestine with perforation and abscess]**

Interventions/Observational Groups

- Arm 1: **Patient survey by questionnaire. All patients will be included who were diagnosed with chronic recurrent diverticular disease and who received inpatient treatment at Schön Klinik Neustadt between Jan 01, 2010 and Dec 31, 2011.**

Characteristics

- Study Type: **Non-interventional**
- 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

health related quality of life measured by the Gastro-intestinal Quality of Life Index (GIQLI) 3-4 years after inpatient treatment

Secondary Outcome

- **frequency of recurrences**
- **time to recurrence**
- **late complications**
- **quality of life after open surgical procedure**
- **quality of life after laparoscopic surgical procedure**
- **frequency of recurrences in men**
- **frequency of recurrences women**
- **proportion of patients with abdominal pain**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- **Medical Center Schön Klinik Neustadt, Neustadt (Holstein)**

Recruitment

- **Planned/Actual: Actual**
- **(Anticipated or Actual) Date of First Enrollment: 2014/06/04**
- **Target Sample Size: 106**
- **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

- **Chronic recurrent diverticular disease**
- **Inpatient treatment at Schön Klinik Neustadt between Jan 01, 2010 and Dec 31, 2011.**



Exclusion criteria

none

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)

Schön Klinik Neustadt, Klinik für Chirurgie und Unfallchirurgie

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

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/09/25**

Trial Publications, Results and other documents

- Paper [---]*

* 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.