Trial Description

Title

Validation of the German Guidelines for Diverticular Disease Conference Classification

Trial Acronym

VADIS

URL of the trial

[---]*

Brief Summary in Lay Language

Clinical experts from different german hospitals have developed a new consensus classification of diverticular disease that included all clinical situations to define an appropriate therapy. This classification aims to improve the therapy of diverticular disease.
The VADIS-Study was designed to explore how well this new classification displays the different states of diverticular disease in clinical routine and if it may augment the clinical decision of adequate therapy.
Patients with CT or endoscopic proven diverticular disease at all stages will be examined, graded according to the new classification and receive adequate therapy.
A follow up will help to asses the quality of clinical diagnostics and therapy.
The study specific procedures consist exclusively of study specific questionaires for complications and quality of life.

Brief Summary in Scientific Language

Diverticular disease is one of the most common diseases in visceral medicine with an incidence of 20 % of the total population.
There are different classifications of diverticular disease although none of them includes all clinical situations appropriatly.
The German Guidelines for Diverticular Disease Conference Classification (GGDDCC) has been designed to overcome this current gap aand classifies the disease as follows:
Typ 0 asymptomatical divericulosis as incidental finding; asyptomatic, no sickness
Typ1 uncomplicated diverticulitis, signs of inflammation obligatory body-imaging with specific result
Typ 1a diverticulitis without ambient reaction, signs of inflammation (biochemical, clinical), ignited diverticulum
Typ 1b diverticulitis with phlegmonous ambient reaction, phlegmonous diverticulitis with intestinal wall edema, peridiverticulits
Typ 2 complicated diverticulisis
Typ 2a microabscess covered perforation, small abscess (< 1cm); minimal paracolic gas
Typ 2b Macroabscess paracolic or mesocolic abscess
Typ 2c open perforation, free gas / liquid, generalized peritonitis
Typ 2c1 purulent peritonitis

Typ 2c2 fecal peritonitis
Typ 3 chronical diverticular disease, recurring or ongoing symptomatical diverticular disease
Typ 3a sympotmatical diverticular disease, DD irritable colon, missing signs of inflammation (labor, clinic, body-imaging)
Tyb 3b recurring diverticulitis without complications
Tyb 3c recurring diverticulitis with complications (e.g. fistula, stenosis, conglomerate tumor)
Typ 4 bleeding from diverticula
VADIS serves as validation of the German Guidelines for Diverticular Disease Conference Classification

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

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Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005576**
- Date of Registration in DRKS: **2013/12/16**
- 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.: **EA4/092/13 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **K57 - Diverticular disease of intestine**

Interventions/Observational Groups

- Arm 1: **Standard anamnesis and physical examination before study inclusion to check the inclusion and exclusion criteria. Standardized documentation of medication, comorbidities and quality of life questionaires after informed consent and study inclusion. Diverticular disease will be categorized according**

to the GGDDCC and the Hansen-Stock-Classification. Anamnesis, physical and technical examinations as well as the potentially performed operation are perforemed according to the current medical guidelines. The additional study procedures consists exclusively on the documentation by study specific questionairies.

- Arm 2: **Retrospective analysis of a historical controll collective of patients with diverticular disease according to the German Guidelines for Diverticular Disease Vonference Classification (GGDDCC) for comparison.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Historical**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

disease-specific complications in long-term-development during 24 months after inclusion

Secondary Outcome

quality of life using SF-36, CGQL und GIQLI, postoperative complications, mortality during 24 months after inclusion

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité Campus Benjamin Franklin, Berlin**
- University Medical Center **Zentrum für Operative Medizin, Würzburg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2013/12/16**
- Target Sample Size: **180**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

CT or colonoscopic proven diverticular disease

Exclusion criteria

1. Impaired cognitive skills to understand the patient information
2. Participation in another clinical trial

Addresses

- **Primary Sponsor**

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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 planned**
- 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.*