

## Trial Description

### Title

**Etiology, Epidemiology and Treatment of Diarrhea and Enterocolitis in Hemato-oncological High Risk Patients (EpiDi)**

### Trial Acronym

**EpiDi**

### URL of the trial

**[---]\***

### Brief Summary in Lay Language

**In patients with cancer, gastrointestinal infections with certain bacteria are associated with severe complications, such as inflammation of the colon, loss of the barrier function of the colonic wall, generalized infection and death. Particularly a certain bacterium called Clostridium difficile seems to play a crucial role in this setting. A new strain of this bacterium, called PCR Ribotyp 027 seems to entail complications or death more frequently than previously observed strains. For this reason, many physicians decide to administer calculated antibiotic therapy with oral metronidazole to patients with abdominal pain or diarrhea after administration of chemotherapy. There are no results from clinical trials, supporting this strategy. Nevertheless, its practice is recommended by the Arbeitsgemeinschaft Infektionen in der Hämatologie und Onkologie (AGIHO) of the Deutschen Gesellschaft für Hämatologie und Onkologie (DGHO). Whether patients truly benefit from this treatment can only be assessed in a controlled, randomized clinical trial. At the moment it's not possible to design such a study, because epidemiological data on does not suffice to calculate the number of patients that would be needed to complete such a trial. In a multicentric observational study, the parameters needed for a reliable case calculation will be documented to assess the feasibility of a clinical trial in this setting. In a multicentric observational study, the parameters needed for a reliable case calculation will be documented to assess the feasibility of a clinical trial in this setting.**

### Brief Summary in Scientific Language

**In hemato-oncological high risk patients, abdominal infections with anaerobic bacteria are associated with severe complications, such as enterocolitis, toxic megacolon, perforation, septic shock and death. Clostridium difficile seems to play a crucial role in this setting. Current reports on the course of abdominal infections with hypervirulent Clostridium difficile PCR Ribotyp 027 strains in Germany and other regions of Europe reported a dramatic rise in morbidity and lethality in association with this pathogen. For this reason, neutropenic patients with diarrhea and/or other signs of abdominal infection are often provided with an empiric course of oral Metronidazole. Even though this strategy is not supported by evidence from clinical trials, its practice is recommended by the Arbeitsgemeinschaft Infektionen**



**in der Hämatologie und Onkologie (AGIHO) of the Deutschen Gesellschaft für Hämatologie und Onkologie (DGHO).**

**The clinical efficacy of this strategy can only be assessed in clinical trials. Due to the heterogeneity of prior studies on the epidemiology and course of these infections, a reliable case calculation is currently not possible.**

**In a multicentric, prospective observational study, the parameters needed for a reliable case calculation will be documented to assess the feasibility of a clinical trial in this setting.**

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

[---]\*

**Description IPD sharing plan**

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00000111**
- Date of Registration in DRKS: **2009/06/16**
- 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.: **09-094 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

## Secondary IDs

## Health condition or Problem studied

- Free text: **Haematologic malignancy**

## Interventions/Observational Groups

- Arm 1: **No intervention**

## Characteristics

- Study Type: **Non-interventional**



Study Type: **Non-interventional**

- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Supportive care**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]\*

#### Primary Outcome

**Incidence of abdominal complications after chemotherapy**

#### Secondary Outcome

**Effect of empiric metronidazole or vancomycin on the incidence of abdominal complications**

#### Countries of recruitment

- DE **Germany**

#### Locations of Recruitment

#### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/06/03**
- Target Sample Size: **400**
- 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**

**Neutropenia  $\geq$  5 days, defined as  $<500$  neutrophils/microL. If no differential blood count available, use  $<1000$  leukocytes/microL**

#### **Exclusion criteria**

- a) **Neutropenia  $<5$  days, defined as  $<500$  neutrophils/microL. If no differential blood count available, use  $<1000$  leukocytes/microL**
- b) **Patients with Colitis ulcerosa, Morbus Crohn or other inflammatory diseases of the colon**
- c) **Patients with diarrhea at admission**
- d) **Patienten, receiving prophylaxis with metronidazole (per os or intravenous) or vancomycin (per os)**

#### **Addresses**

##### ■ **Primary Sponsor**

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### Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**DFG**

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### 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.