

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Study to Evaluate Central venous Catheter-related Infections in Hematology and Oncology

Trial Acronym

SECRECY

URL of the trial

[---]*

Brief Summary in Lay Language

Central venous catheter-related infections are a frequent problem in hematology and oncology. Due to different definitions of such infections, because there are many different institutions and medical societies, it is difficult to compare data regarding these infections. In 2014, the Infectious Diseases Working Party of the German Society of Hematology and Medical Oncology has revised the definitions. Epidemiological data based on these current definitions are not available so far. Therefore, in this registry epidemiological data and risk factors for these infections will be documented. Furthermore, using the Infectious Probability Score prediction of these infections will be made.

Brief Summary in Scientific Language

Central venous catheters (CVC) are widely used in hematology and oncology. Cancer patients, by different risk factors are at high risk in terms of CVC infections (catheter-related infections, CRI), associated with increased morbidity, mortality, and hospital costs. The diagnosis of CRI is based on clinical symptoms and laboratory constellations that can withstand not always clear definitions. In the literature, there are different definitions of CRI published by different institutions and medical societies. The risk of infection varies between catheter type, insertion site, immunocompetence, number of days of CVC in use and other factors. The Infectious Diseases Working Party (AGIHO) of the German Society of Hematology and Medical Oncology (DGHO), had created CRI definitions that are consistent with international medical societies as well as easy to use in the clinic. The AGIHO distinguishes between definite, probable and possible catheter-related blood stream infections (CRBSI). Due to different definitions, different not clearly comparable epidemiological data on CVC infections exist. Epidemiological data based on the current AGIHO criteria (2014), have not yet been generated or published. One objective is therefore to generate these epidemiological data by a prospective observational study. Since the diagnosis of CVC infections can often be made only when the CVC has already been removed, the question arises whether there is a symptom or parameter constellation that could indicate or exclude such infection. With the Infection Probability Score (IPS), the presence or absence of infections can be predicted in critically ill patients. For the IPS the

simply and widely used parameters body temperature, heart rate, blood pressure, leukocytes, C-reactive protein and parameters of the Sequential Organ Failure Assessment (SOFA) score are used. A score of 14 was determined as cut-off. Patients who had a score <14 have a risk of 10% only for infection [negative predictive value (NPV) = 90%]. Using the IPS, infections can be excluded with high probability. In the following, the IPS was examined in various, mostly intensive care scenarios. Specifically on the issue of CVC infections using the IPS, there are still no published data.

This study is a non-interventional, prospective observational/cohort study. As cohort was defined all patients, who were treated in the Department of Hematology and Oncology receiving a CVC for treatment of any kind. Through this observation study, the following questions are answered and the following data are generated: calculation of prevalence and incidence of CRBSI according to the current AGIHO definitions (with differentiation in definite, probable and possible CRBSI); identification of risk factors that favor CVC infections; application of the IPS and calculating a cut-off for the detection/exclusion of CRBSI; documentation of the germ spectrum, which led to CRBSI; documentation of complications of CVC insertion as well as in the course of use.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006551**
- Date of Registration in DRKS: **2014/09/29**
- 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.: **84/14 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1159-9019**

Health condition or Problem studied

- ICD10: **T82.7 - Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts**

Interventions/Observational Groups

- Arm 1: **Evaluation of epidemiological data and risk factors on infections due to central venous catheters (CVC)**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Prevalence and incidence of CVC infections (CRBSI, catheter-related bloodstream infections) in hematology and oncology (using the AGIHO/DGHO 2014 criteria); using the Infection Probability Score (IPS) and determine a cut-off value for CVC infection

Secondary Outcome

Risk factors; germ spectrum; complications

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Magdeburg, Klinik für Hämatologie und Onkologie, Magdeburg**
- University Medical Center **Universitätsmedizin Mainz, III. Medizinische Klinik und Poliklinik, Mainz**
- Medical Center **Rotkreuzklinikum München, Abteilung für Innere Medizin III, München**

- University Medical Center **Uniklinik RWTH Aachen, Klinik für Hämatologie, Onkologie, Hämostaseologie und Stammzelltransplantation, Aachen**
- University Medical Center **Uniklinik Köln, Klinik für Innere Medizin I - Onkologie, Hämatologie, Klinische Infektiologie, Klinische Immunologie, Hämostaseologie, Internistische Intensivmedizin, Köln**
- Medical Center **Carl-Thiem-Klinikum, 2. Medizinische Klinik - Hämatologie/Internistische Onkologie, Cottbus**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/04/22**
- Target Sample Size: **3000**
- 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

In-patient therapy in the Department of Hematology and Oncology; indication for CVC insertion for therapeutic intention; informed consent for CVC insertion for therapeutic intention

Exclusion criteria

None

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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E-mail: [---]*

URL: **www.med.uni-magdeburg.de**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- Paper **Annals of Hematology**
- Paper **Infection Control & Hospital Epidemiology**
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* 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.