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

Trial Description

Title

“Incidence and outcome of invasive fungal infections in pediatric patients with hematological malignancies and/or undergoing allogeneic hematopoietic stem cell transplantation – a prospective analysis in three major pediatric cancer centers (IFI-PED Study)”

Trial Acronym

IFI-PED

URL of the trial

[---]*

Brief Summary in Lay Language

Current data on the incidence and on the outcome of invasive fungal infections in children with leukemia and/or hematopoietic stem cell transplantation are scarce. Most available data stem from studies performed prior to the availability of newer antifungal drugs. We plan to perform a prospective multicenter study on the frequency and prognosis of invasive fungal infections in children at high risk for invasive fungal infections and on the use of antifungal compounds in this population. We will collect data on patients´characteristics (such as age, underlying malignancy, chemotherapy), results of diagnostic procedures as well as on the use of antifungal compounds (such as for prophylaxis, empirical treatment or treatment of proven invasive fungal infections). These data will be analyzed regarding incidence of invasive fungal infections. In addition, we plan to characterize risk factors and periods of particular high risk for fungal infections and the current prognosis of these infectious complications when new antiufungal agents are available.

Brief Summary in Scientific Language

Current data on the incidence and on the outcome of invasive fungal infections in children with hematological malignancies (HM) and/or allogeneic hematopoietic stem cell transplantation (HSCT) are scarce. Most available data stem from studies performed prior to the availability of newer triazoles such as voriconazole or echinocandins such as caspofungin and micafungin. In addition, many studies were performed retrospectively or are based on data of a single institution. We therefore plan to perform a prospective multicenter study on the frequency and prognosis of invasive fungal infections in children at high risk for invasive fungal infections and on the use of antifungal compounds in this population. We will collect data on patients´characteristics (such as age, underlying malignancy, chemotherapy, duration of neutropenia), results of diagnostic procedures, which may indicate or prove an invasive fungal infection (e.g., blood culture, galactomannan, imaging studies) as well as on the use of antifungal compounds (such as for prophylaxis, empirical treatment or treatment of proven invasive

fungal infections). These data will be analyzed regarding incidence of possible, probable, and proven invasive fungal infections. In addition, we plan to characterize risk factors and periods of particular high risk for fungal infections and the current prognosis of these infectious complications when new antiufungal agents are available.

Organizational Data

- DRKS-ID: **DRKS00006341**
- Date of Registration in DRKS: **2014/07/21**
- 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.: **348/13 , Ethikkommission des Fachbereichs Humanmedizin der Johann-Wolfgang-Goethe-Universität Frankfurt am Main**

Secondary IDs

Health condition or Problem studied

- Free text: **Children with hematological malignancy (C91.0; C92.0)/children undergoing hematopoietic stem cell transplantation; proven, probable, and possible invasive fungal infection (B49)**
- ICD10: **B49 - Unspecified mycosis**
- ICD10: **C92.0 - Acute myeloblastic leukaemia [AML]**
- ICD10: **C91.0 - Acute lymphoblastic leukaemia [ALL]**

Interventions/Observational Groups

- Arm 1: **Children with hematological malignancy/children undergoing hematopoietic stem cell transplantation; data captured include age, underlying malignancy, temperature; diagostic ruslts (e.g., galactomannan, imaging studies); administration of antifungal compounds**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Single arm study**
- Blinding: **[---]***

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Study Type Non-Interventional: **Epidemiological study**

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Blinding: **[---]***

- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

to describe the epidemiology of invasive fungal infections in three major pediatric cancer centers in Germany/Austria

Secondary Outcome

1) to characterize risk factors and periods of risk for invasive fungal infections in different pediatric patient populations (e.g., children suffering from ALL, AML etc)
2) outcome of invasive fungal infections in pediatric cancer patients

Countries of recruitment

- DE **Germany**
- AT **Austria**

Locations of Recruitment

- Medical Center **Klinik für Kinder- und Jugendmedizin der Universität, Frankfurt a.M.**
- Medical Center **Pädiatrische Hämatologie und Onkologie der Universität, Münster**
- Medical Center **St.Anna Kinderspital, Wien**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/04/01**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2014/04/01**

- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **0 Days**
- Maximum Age: **18 Years**

Additional Inclusion Criteria

• Children and adolescents 0 to <18 years who are diagnosed with acute lymphoblastic leukemia, acute myeloid leukemia, relapse of acute leukemia or receive an allogeneic hematopoietic stem cell transplantation in the University Children´s Hospitals of Frankfurt, Münster or in St. Anna Kinderspital, Vienna, respectively
• Diagnosis of the malignancy/ transplantation between April 1, 2014 and March 31, 2016
• Written informed consent is mandatory for enrollment in the study.

Exclusion criteria

• Patients without written informed will be excluded from the study.

Addresses

- **Primary Sponsor**

  Pädiatrische Hämatologie und OnkologieKlinik für Kinder- und JugendmedizinJohann Wolfgang Goethe Universität
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  60590 Frankfurt
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  URL: **[---]***
- **Contact for Scientific Queries**

Contact for Scientific Queries

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■ **Collaborator, Other Address**

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Sources of Monetary or Material Support

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

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Germany

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

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Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.kgu.de**

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.*