Trial Description

Title

(1,3)-β-D-glucan based diagnosis of invasive candida infection versus culture based diagnosis in patients with severe sepsis or septic shock and a high risk for invasive candida infection.

Trial Acronym

CandiSep

URL of the trial

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Brief Summary in Lay Language

Critically ill patients with severe infections are in need of a broad antibiotic therapy. However, severe fungal infections are rather rare and should only be treaded if proven. Proof of fungal infections takes several day - time which is lost for adequate treatment. An untreated fungal infection is a high risk for critically ill patients. (1,3)-β-D-glucan (BDG) is part of many fungi and appears fast in the blood of infected patients. Several studies already used measurement of BDG to diagnose severe fungal infections. However, it is controversial whether this test works on an intensive care unit. This study investigates whether BDG measurements in critically ill patients facilitates an early antifungal therapy.

Brief Summary in Scientific Language

(1,3)-β-D-glucan is a component of the cell wall of many fungi including candida spp. and is present in the blood of patients with invasive candida infection (ICI). Several studies showed a good diagnostic accuracy (1,3)-β-D-glucan in predicting ICI. However, others have challenged (1,3)-β-D-glucan as a diagnostic tool in critically ill patients as many substances used in the intensive care unit might affect the results of the assay. The goal of this study is to investigate whether (1,3)-β-D-glucan can early identify sepsis patients in need of antifungal therapy. Patients randomized to the standard of care group receive antifungals depending on microbiological results according to current guidelines. Patients randomized to the BDG group receive antifungals depending on the (1,3)-β-D-glucan plasma concentration on day 1 and day after diagnosing sepsis. Therapy may be modified according to microbiological results.

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

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Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00010285**
- Date of Registration in DRKS: **2016/08/22**
- Date of Registration in Partner Registry or other Primary Registry: **2016/04/06**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **4754-04/16 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1181-8724**
- Primary Registry-ID: **NCT02734550 (Clinicaltrials.gov)**

Health condition or Problem studied

- ICD10: **A41 - Other sepsis**
- Free text: **Severe sepsis, septic shock**

Interventions/Observational Groups

- Arm 1: **Standard of care: Patients are treated according to the ESCMID guidelines. Antifungal therapy is started if fungi are detected in the blood culture or other primary sterile body fluids.**
- Arm 2: **(1,3)-β-D-glucan guided therapy: In addition to standard care, serum for (1,3)-β-D-glucan measurement is obtained after enrollment and 24 hours later. Antifungal therapy is started if at least one sample is 80 pg/ml or higher. If concomitantly taken microbiological cultures remain negative, antifungal therapy is continued only, if both (1,3)-β-D-glucan were at least 80 pg/ml. Blood cultures or other samples from primary sterile bod fluids positive for fungi are treated with antifungals irrespective the (1,3)-β-D-glucan results.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***

Study Type: **Interventional**

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Allocation: **Randomized controlled trial**

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

Who is blinded: **[---]***

- Control: **Active control (effective treament of control group)**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

28-day mortality

Secondary Outcome

28-day antifungal free survival, candida colonization, time to antifungal therapy, duration of organ support, 14 days mean total SOFA score, ICU und hospital length of stay, ICU ans hospital survival, adverse events, diagnostic accuracy of (1,3)-β-D-glucan in comparison to candida PCR and other experimental diagnostics, paracoeconomic analyses

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinikum Augsburg, Augsburg**
- Medical Center **Klinikum Emden, Emden**
- University Medical Center **Universitätsklinikum Göttingen, Göttingen**
- University Medical Center **Universitätsmedizin Greifswald, Greifswald**
- University Medical Center **Universitätsklinikum Frankfurt, Frankfurt a.M.**
- University Medical Center **Universitätsklinikum Hamburg-Eppendorf, Hamburg**
- University Medical Center **Universitätsklinikum Heidelberg, Heidelberg**

- University Medical Center **Universitätsklinikum Jena, Jena**
- University Medical Center **Universitätsklinikum Schleswig-Holstein, Campus Kiel, Kiel**
- University Medical Center **Universitätsklinikum Leipzig, Leipzig**
- University Medical Center **Klinikum Oldenburg, Oldenburg**
- University Medical Center **Bonn**
- Medical Center **HELIOS Klinikum Bad Saarow, Bad Saarow**
- University Medical Center **Universitätsklinikum Erlangen, Erlangen**
- Medical Center **Diakonie Klinikum, Siegen**
- University Medical Center **Universitätsklinikum Halle(Saale), Halle Saale**
- University Medical Center **Münster, Münster**
- University Medical Center **Würzburg, Würzburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/09/13**
- Target Sample Size: **312**
- 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

Severe sepsis or septic shock
Increased risk for invasive candida infection (at least one of the following):
> total parenteral nutrition ≥48 hours
> abdominal surgery within the last 7 days
> antimicrobial therapy for at least 48 hours within the last 7 days
> Acute or chronic renal failure with renal replacement therapy
Onset of sepsis no longer than 24 hours
Age ≥18 years
Informed consent of the patient or legal representative or delayed consent process is started if patient is incapable of giving informed consent and no legal representative is available.

Exclusion criteria

Pregnant or lactating women
Ongoing invasive candida infection
systemic antifungal therapy
liver cirrhosis Child C
cardiopulmonary bypass within the last 4 weeks
treatment with immunoglobulins within the last 14 days
immunosuppression (solid organ transplantation, AISA, leukopenia)
participation in another intervention study
no commitment to full therapy (i.e. DNR order)
Infauste Prognose aufgrund von Nebenerkrankungen
Kin to or colleague of study personnel

Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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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.)**

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■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/09/17**

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.*