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

Trial Description

Title

Influence of low-dose acetylsalicylacid on the treatment result of patients with pneumonia (benefit of ASS with CAP) - a retrospective data analysis

Trial Acronym

BACAP

URL of the trial

[---]*

Brief Summary in Lay Language

An overshooting coagulation activation results, especially with systemic inflammatory reactions, in microthrombosis and organ failure. Coagulation inhibitors like acetylsalicylic acid can evidently improve the treatment results with critical ill patients. Patients with pneumonia are jeopardized to develop complications like a systemic inflammatory reaction or organ failure being accompanied with an increased mortality rate. In our study we investigate the effect of a pre-existing permanent therapy of acetysalicylic acid on the therapy result of patients who have been admitted to hospital as inpatients with pneumonia. Considering comorbidty and comedication, the primary endpoints of this retrospective data analysis are: hospital mortality, organ failure and sepsis; secondary endpoints are: length of stay in hospital and on intensive care unit (ICU) as well as occurence of arterial and venous thrombosis and bleeding complications.

Brief Summary in Scientific Language

An overshooting platelets (thrombocytes) activation results, especially with systemic inflammations, in microvascular thrombosis and organ failure. Thrombocytes aggregation inhibitors (anti-platelet agents) like acetylsalicylic acid inhibit the activation of thrombocytes and can evidently improve the treatment results with critical ill patients. Patients with pneumonia are jeopardized to develop complications like a systemic inflammation or organ failure being accompanied with an increased mortality rate. In our study we investigate the effect of a pre-existing cardiovascular induced permanent therapy of acetysalicylic acid on the therapy result of patients who have been admitted to hospital as inpatients with pneumonia. Considering comorbidty and comedication, the primary endpoints of this retrospective data analysis are: hospital mortality, organ failure and sepsis; secondary endpoints are: length of stay in hospital and on intensive care unit (ICU) as well as occurence of arterial and venous thromboembolism and bleeding complications.

Organizational Data

- DRKS-ID: **DRKS00007626**
- Date of Registration in DRKS: **2015/02/05**
- 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.: **3750-04/13 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

Secondary IDs

Health condition or Problem studied

- ICD10: **J18 - Pneumonia, organism unspecified**
- ICD10: **R65 - Systemic Inflammatory Response Syndrome [SIRS]**
- ICD10: **A41 - Other sepsis**
- ICD10: **R57.2 - Septic shock**

Interventions/Observational Groups

- Arm 1: **patients without low-dose acetylsalicylic acid therapy, retrospective data analysis**
- Arm 2: **patients with low-dose acetylsalicylic acid permanent therapy, retrospective data analysis**
- Arm 3: **patients with newly onset of low-dose acetylsalicylic acid therapy, retrospective data analysis**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **No treatment**
- Purpose: **Prognosis**
-

Study Type: **Non-interventional**

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

Allocation: **Non-randomized controlled trial**

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

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

Control: **No treatment**

Purpose: **Prognosis**

Assignment: **Parallel**

- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

1. mortality during hospital stay; 2. Organ failure (incl. considering pre-existing organ dysfunctions) in the time period concerned; 3. occurence of SIRS or sepsis or septic shock

Secondary Outcome

1. duration (days) of hospital and ICU stay considering geriatric treatments; 2. occurence of haemostaseologic and bleeding complications; 3. maximum for APACHE II and SOFA score of ICU patients

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Jena**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/04/27**
- Target Sample Size: **365**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Pneumonia

Exclusion criteria

1. hospital stay <4 days; 2. transfer from another hospital; 3. pregnancy; 4. diagnosis of lung cancer; 5. diagnosis of tuberculosis

Addresses

- **Primary Sponsor**

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  07740 Jena
  Germany

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  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.uniklinikum-jena.de**

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- **Collaborator, Other Address**

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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.)**

BMBF
10117 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/12/10**

Trial Publications, Results and other documents

- Paper **[---]***

** 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.*