DIANA Study - DetermInants of Antimicrobial use aNd de-escalAtion in critical care

Summary of the rationale

De-escalation of empirically started antibiotics is applied in no more than 15-50% of patients in most studies, and may consist of different components. There may be important differences between hospitals and countries in the use of de-escalation as well as the impact on outcome thereof. Large scale, multi-country studies are currently lacking.

Target

This study from the Infection Section of European Society of Intensive Care Medicine (ESICM) aims to include 2000 patients in whom empirical antibiotics are started. With an estimated de-escalation rate of 35%, we estimate to include 700 patients in whom de-escalation is performed which

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and methods of administration across ICUs. • To describe the approaches to de-escalation used in critically ill patients. • To describe microbiological, infection, patient, physician, ICU- and country-related characteristics associated with de-escalation. • To describe factors associated with positive outcomes in de-escalated patients. • To describe the effect of de-escalation on the use of broad-spectrum antimicrobials, the total dose of antimicrobials and duration of treatment. • To describe the effect of de-escalation on the emergence of MDR infection and colonization.

How do I participate?

For more information visit the webpage:

www.dianastudy.ugent.be

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the Intensive Care Unit (ICU). • Given the explorative nature of this study the required number of patients was not calculated. We aim to include 2000 patients in whom empirical antibiotics are started. With an estimated de-escalation rate of 35%, we estimate to include 700 patients in whom de-escalation is performed which would allow for a suitable multivariable analysis. Study duration • Patients will be included in the participating centers during a 2-week inclusion period. • Patients will be observed until 28 days after inclusion in the study. Primary objective(s) • To describe the empirical antibiotic therapy for infections at the ICU. • To describe the rate of de-escalation as well as the associated outcome (mortality, length of stay on ICU, hospital length of stay, infection relapse, subsequent infection). Secondary objective(s) • To describe appropriateness of empirical antimicrobial therapy in critically ill patients. • To describe duration of empirical and directed antimicrobial therapy in critically ill patients. DetermInants of Antimicrobial use aNd de-escalAtion in critical care (DIANA study)- Study Protocol Study protocol version October 2016 Page 5 • To describe variability in antibiotic dosing would allow for a suitable multivariable analysis.

The trial will give us further insights into the actual use of de-escalation in a global sample of patients, inform us about the determinants of de-escalation, as well as describe the impact of de-escalation, taking various potential confounders into account.

Study Start Date

2nd semester of 2016

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Protocol

SUMMARY OF THE STUDY Study title • DetermInants of Antimicrobial use aNd de-escalAtion in critical care (DIANA study) Study design • Multicenter, international, prospective, observational cohort study Patient population • Critically ill patients receiving empirical antibiotic therapy for suspected or confirmed infections at