Procalcitonin to guide duration of antibiotic therapy in intensive care patients

| Submission date | Recruitment status No longer recruiting | | Рго |
|-------------------|---|-----------|------|
| 19/02/2009 | | | Рго |
| Registration date | Overall study status | \square | Stal |
| 24/02/2009 | Completed | [X] | Res |
| Last Edited | Condition category | | Indi |
| 24/01/2020 | Infections and Infestations | | |

spectively registered

tocol

tistical analysis plan

sults

vidual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr Stefan Schroeder

Contact details West Coast Hospital Department of Anaesthesiology and Intensive Care Medicine Esmarchstr. 50 Heide Germany 25746

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Procalcitonin to guide duration of antibiotic therapy in intensive care patients: a randomised controlled single-centre trial

Study objectives Daily serum procalcitonin determination reduces length of antibiotic therapy.

Ethics approval required Old ethics approval format

Ethics approval(s) Ethics Committee of Medical Faculty, Christian Albrecht University of Kiel, approved on 01/12 /2005 (ref: A158/05)

Study design Randomised controlled single-centre trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Bacterial infection in intensive care patients

Interventions

Patients were randomly assigned to either a Procalcitonin (PCT)-guided (study group) or a standard (control group) antibiotic regimen. For both groups antibiotics were selected upon confirmed or highly suspected bacterial infections.

Antibiotic therapy in the PCT-guided group was discontinued if clinical signs and symptoms of infection improved and 1) PCT decreased to <1 ng/ml or 2) the PCT value was >1 ng/ml, but had dropped to 25-35% of the initial value over 3 days.

In the control group antibiotic treatment was applied as standard regimen over 8 days.

Irrespective of the study group and at any time point, the physician in charge had the option to proceed with or adjust the antibiotic treatment, if there were clinical reasons to do so.

Intervention Type Other **Phase** Not Applicable

Primary outcome measure Duration of antibiotic therapy.

Secondary outcome measures No secondary outcome measures

Overall study start date 01/01/2006

Completion date 31/03/2007

Eligibility

Key inclusion criteria

All patients (both males and females, >18 years) requiring antibiotic therapy based on confirmed or highly suspected bacterial infections and at least 2 concomitant Systemic Inflammatory Response Syndrome (SIRS) criteria.

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 110

Total final enrolment 110

Key exclusion criteria

- 1. Patients who refused study consent
- 2. Patients whose antibiotic treatment had been initiated before intensive care admission
- 3. Patients who had therapy limitations

Date of first enrolment

01/01/2006

Date of final enrolment 31/03/2007

Locations

Countries of recruitment Germany

Study participating centre West Coast Hospital Heide Germany 25746

Sponsor information

Organisation Westküstenkliniken [West Coast Hospitals]

Sponsor details Esmarchstr.50 Heide Germany 25746

Sponsor type Hospital/treatment centre

Website http://www.wkk-online.de

Funder(s)

Funder type Hospital/treatment centre

Funder Name Westküstenkliniken [West Coast Hospitals]

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------|---------|--------------|------------|----------------|-----------------|
| <u>Results article</u> | results | 01/06/2008 | | Yes | No |
| Results article | results | 01/06/2009 | | Yes | No |