ISRCTN10288268 https://doi.org/10.1186/ISRCTN10288268

Procalcitonin to guide duration of antibiotic therapy in intensive care patients

Submission date
19/02/2009

Recruitment status
No longer recruiting

Registration date
24/02/2009

Overall study status
Completed

Last Edited
24/01/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Duration of antibiotic therapy.

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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]

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Westküstenkliniken [West Coast Hospitals]

Results and Publications

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?
Results article	results	01/06/2008		Yes	No
Results article	results	01/06/2009		Yes	No