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Procalcitonin to guide duration of antibiotic therapy in intensive care patients

Submission date	Recruitment status	[_] Prospectively registered
19/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2020	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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