

Procalcitonin to guide duration of antibiotic therapy in intensive care patients

Submission date 19/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/02/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/01/2020	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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