ISRCTN70694559 https://doi.org/10.1186/ISRCTN70694559

Clinical value of LightCycler® SeptiFast Test compared to conventional blood cultures for antimicrobial detection in post-surgical septic patients

Submission date
17/07/2009

Recruitment status
No longer recruiting

Registration date
18/09/2009

Overall study status
Completed

Last Edited
19/02/2016

Condition category
Injury, Occupational Diseases, Poisoning

[X] 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
Prof Claudia Spies

Contact details
Department of Anaesthesiology and Intensive Care Medicine
Augustenburger Platz 1
Berlin
Germany
13353
+49 (0)30 450 55 10 01
claudia.spies@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EA1/043/09

Study information

Scientific Title
Clinical value of LightCycler® SeptiFast Test compared to conventional blood cultures for antimicrobial detection in post-operative septic patients: a prospective, randomised single-centre trial

Acronym
SeptiFast

Study objectives
Antimicrobial detection in septic patients with the LightCycler® SeptiFast Test leads to accelerated administration of appropriate antibiotic therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Charité - University Medicine Berlin, 12/03/2009, ref: EA1/043/09

Study design
Prospective randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sepsis due to abdominal infection or hospital acquired pneumonia

Interventions
Patients will be randomised in two groups. Samples for the LightCycler® SeptiFast Test will be taken in both groups parallel to conventional blood cultures. In group 1, the results of the LightCycler® SeptiFast Test will be made available for the treating physician, in group 2, results of the LightCycler® SeptiFast Test will be analysed retrospectively. Both groups will be assessed

for changes in the initial empirical therapy (end of intervention), both groups will be followed up until resolution of all clinical signs of sepsis or discharge from the Intensive Care Unit (ICU) or for a maximum period of 30 days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Frequency of changes of the initial antibiotic treatment related to diagnostic procedures and time until appropriate antibiotic treatment, assessed at the end of data collection.

Secondary outcome measures
1. Rate of patients with organisms detected by the LightCycler® SeptiFast Test compared to all patients with clinically confirmed sepsis
2. Rate of empirical treatment that was retrospectively confirmed to be appropriate
3. Number of days with antibiotic treatment
4. Decreasing severity of illness (Simplified Acute Physiology Score [SAPS], Sequential Organ Failure Assessment [SOFA], 28-item Therapeutic Intervention Score [TISS-28]) during treatment
5. Length of mechanical ventilation
6. Length of intensive care unit (ICU) stay
7. Length of hospital stay
8. Therapy costs

All assessed at the end of data collection.

Overall study start date
01/01/2007

Completion date
30/04/2012

Eligibility

Key inclusion criteria
1. Post-surgical patients with suspected intra-abdominal infection or hospital acquired pneumonia
2. Suspected or known infection that clinically indicates investigation by blood cultures
3. Inclusion within 72 hours of diagnosis
4. Presence of at least two criteria for systemic inflammatory response syndrome (SIRS):
4.1. Temperature greater than 38°C or less than 36°C
4.2. Heart rate greater than 90 beats/minute
4.3. Respiratory rate greater than 20 breaths/minute or partial pressure of carbon dioxide in arterial blood (PaCO2) less than 32 mmHg/4.3 kPa
4.4. White blood cell count (WBC) greater than 12.000/mm^3 or less than 4.000/mm^3 or 10% immature
5. Age greater than 17 years, either sex

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Moribund patients with expected survival less than 24 hours
2. Less than 18 years of age
3. Pregnancy
4. Known and confirmed organism responsible for infection
5. Participation in an other prospective clinical study during the passed 30 days
6. Consent of the patient or legal guardian cannot be obtained

Date of first enrolment
11/08/2010

Date of final enrolment
29/03/2012

Locations

Countries of recruitment
Germany

Study participating centre
Department of Anaesthesiology and Intensive Care Medicine
Berlin
Germany
13353

Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Sponsor details

Chariteplatz 1
Berlin
Germany
10117

Sponsor type
Hospital/treatment centre

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Charité Universitätsmedizin Berlin

Alternative Name(s)
Medical School - Charité - University Medicine Berlin

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

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	01/06/2015		Yes	No