

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	☒ Prospectively registered ☐ Protocol
Registration date 18/09/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/02/2016	Condition category Injury, Occupational Diseases, Poisoning	☐ 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
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

Primary study design

Interventional

Study design

Prospective randomised controlled single-centre trial

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

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.

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/mm³ or less than 4.000/mm³ or 10% immature
5. Age greater than 17 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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