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Influence of applying molecular methods in diagnostics and treatment of bloodstream infections

Submission date
08/08/2022

Recruitment status
No longer recruiting

Registration date
11/01/2023

Overall study status
Completed

Last Edited
10/01/2023

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Bloodstream infections are associated with high mortality, frequently connected with the delayed or inadequate implementation of antimicrobial therapy. Furthermore, the timing of the microbiological tests plays a key role in determining optimal therapeutic decisions. Although conventional blood culture remains the gold diagnostic standard, molecular methods play an increasingly important role in modern clinical microbiology. In practice, molecular methods are most beneficial if they are used in conjunction with an antimicrobial stewardship program, and the obtained results are properly interpreted and lead to appropriate therapeutic decisions.

Who can participate?
Both female and male adult patients with positive blood cultures can participate in this study.

What does the study involve?
Comparing two ways of diagnosing bloodstream infections: standard diagnostic procedure and molecular testing based on BioFire blood culture identification.

What are the possible benefits and risks of participating?
Providing faster and more accurate diagnosis of bloodstream infections and implementing more optimal therapeutic procedures.

Where is the study run from?
4th Military Clinical Hospital in Wroclaw (Poland)

When is the study starting and how long is it expected to run for?
July 2022 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Patrycja Leśnik, plesnik@4wsk.pl

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

Nil known

Study information

Scientific Title
Evaluation of the clinical benefits resulting from the application of the BIOFIRE® Blood Culture Identification 2 (BCID2) Panel in diagnostics and treatment of bloodstream infections among hospitalized patients

Study objectives
Molecular methods used in diagnosing bloodstream infections have a beneficial effect on the effectiveness of the treatment process. In conjunction with Antimicrobial Stewardship Program will lead to a reduction in the use of broad-spectrum antibiotics and therefore decrease the frequency of post-antibiotic complications such as C.difficile diarrhea

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/07/2022, Bioethics Committee of the Military Institute of Medicine (Jana Pawła Woronicza 15, 02-625, Warsaw, Poland; no telephone number provided; no email provided), ref: approval no. KB 45/21, resolution no. WIL 240/22

Study design
Single-center interventional double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Positive blood culture

Interventions
A total of 150 patients are planned to be enrolled in the study, randomly allocated with a 2:1 ratio into two groups (group A: 100 patients included in the study group with molecular testing BCID2 and group B: 50 patients included in the control group without molecular testing).
The study enrolled consecutive adult patients, irrespective of gender, who will have a positive blood culture. Written consent to participate in the study was obtained.
Upon obtaining a positive blood culture on the analyzer, BacT/ALERT (Biomerieux) patients will be randomly assigned into one of two comparative groups: A and B.
In group A, after BCID2 results, laboratory staff will consult with a medical professional who coordinates the study from clinical aspects. In group B, only the traditional method of microbial culture and determination of identification and susceptibility testing will be used.
The physician will be responsible for filling out an information questionnaire and implementing antibiotic stewardship recommendations, for example, receipt of an anti-MRSA agent, antipseudomonal B-lactam agent, narrow-spectrum B-lactam agent, or de-escalation therapy from vancomycin to cloxacillin in case of Staphylococcus aureus MSSA. In the hospital, there are

internal procedures for AMS, which can be implemented in most cases. If there are no such procedures for specific cases, the procedure is established based on the National Antibiotic Protection Program. The analysis will cover demographic data, age, sex, the existence of chronic diseases, and the antibiotic therapy used so far. Additionally, the following biochemical parameters will be analyzed: WBC, PLT, CRP, PCT, Creatinine, Urea, arterial blood gas, milk level, and SOFA scale. Additionally, the following clinical values will be analyzed: patient's clinical condition, heart rate, diuresis, and arterial blood pressure. The analysis will also cover the time of taking the culture, starting empiric antibiotic therapy, its type, and then the duration of treatment, and the time of starting the therapy. Target, time, and doses of drugs. The hospitalization time/length of stay will also be recorded.

Intervention Type
Mixed

Primary outcome(s)
1. Time to optimal antimicrobial therapy [Time Frame: 21 days]
Calculated from the time of blood culture draw to the laboratory to the time the optimal antimicrobial therapy is started. Optimal antimicrobial therapy is defined based on hospital guidelines.

Key secondary outcome(s))
Measured using patient records unless indicated:
1. Time to organism identification [Time Frame: 7 days]
Calculated from the time of blood culture draw to the time of organism identification.
2. Time to effective antimicrobial therapy [Time Frame: 14 days]
Calculated from the time of blood culture draw to the time the effective therapy is started. Effective therapy is determined based on the susceptibilities of the organism.
3. Infectious -cause mortality [Time Frame: 30 days]
4. Length of hospital stay [Time Frame: 30 days]
5. Episodes of Clostridioides dificille [Time Frame: 30 days]
6. Intensive care unit days [Time Frame: 30 days]
7. Time to De-escalation from brad-spectrum therapy to the targeted agent [Time Frame: 7 days]
8. Time to Discontinuation of the therapy due to the identification organism being a contaminant [Time Frame: 14 days]

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Positive blood culture will be eligible for the study
2. Two sets of blood (2x aerobic, 2x anaerobic)
3. Age >18 years
4. Informed consent form to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age under 18 years
2. Refusal to participate in the study
3. Positive blood culture for the 72 hours follow-up (ex. for Staphylococcus aureus bacteriemia).
4. Patients with blood PCR tests ordered outside the established research protocol and the established randomization. (PCR test ordered by the attending physician due to the patient's severe condition). * in our hospital, the doctor can order a PCR test from blood on his own in the case of a patient in a life-threatening condition, in shock, or for other reasons. Such patients will not be eligible for our study. They may constitute an interesting group of patients in the future, which can be compared with group A planned by our team, where, in addition to the blood PCR test, consultations will be provided on the correct treatment with the appropriate selection of ATB as well as the dosage and duration of treatment.

Date of first enrolment
01/09/2022

Date of final enrolment
21/12/2023

Locations

Countries of recruitment
Poland

Study participating centre
4th Military Clinical Hospital
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Sponsor information

Organisation
bioMérieux SSC Europe Sp. z o. o.

Organisation
4th Military Clinical Hospital in Wroclaw

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. patrycja.lesnik@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes