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Effect of exclusion of bacteremia on antibiotic treatment

Submission date	Recruitment status	[X] Prospectively registered
02/11/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/11/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/01/2020	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The number of infections caused by bacteria resistant to a range of antibiotics is increasing rapidly and treatment of some infections is becoming difficult. The greatest risk is in critically ill patients in the intensive care unit. Most of those patients are given antibiotics as a precautionary measure to avoid infection. If the antibiotics are not needed and can be stopped however, the risk of the patient developing infections that are resistant to antibiotics later can be reduced. If a test could rule out the presence of bacteria in the blood within 24 hours, the doctor may be able to stop antibiotic treatment at 24 or 48 hours

Who can participate?
Adults in ICU who are having blood samples taken to test for a suspected infection.

What does the study involve?
All participants have an additional blood sample taken when they are having routine samples taken. This sample is then tested in the lab using a kit that can show there are no bacteria in the sample. After 24 and 48 hours, the treating doctor is asked whether or not the information gained from the test would change the length of time antibiotics are given to that patient for.

What are the possible benefits and risks of participating?
A possible benefit may be having an increased chance of detecting infections in patient samples, as an additional sample is taken. There are no risks associated with the study.

Where is the study run from?
University College London Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2016 to June 2017

Who is funding the study?
Momentum Bioscience Ltd (UK)

Who is the main contact?
Dr Andrew Peter Wilson
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31765

Study information

Scientific Title
Observational study in critical care to assess if use of a diagnostic test to exclude bacteremia would affect clinical decision making

Study objectives
The aim of this study is to compare the performance of Enzymatic Template Generation & Amplification (ETGA) to conventional clinical and microbiological evaluation in determining length of antibiotic treatment in patients in the critical care unit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 4, 09/09/2016, ref: 16/WA/0264

Study design
Non-randomised; Both; Design type: Diagnosis, Device, Validation of investigation /therapeutic procedures

Primary study design
Observational

Secondary study design
Cohort study

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
Specialty: Critical care, Primary sub-specialty: Critical care; UKCRC code/ Disease: Inflammatory and Immune System/ Other diseases of blood and blood-forming organs, Infection/ Bacterial, viral and other infectious agents

Interventions
All patients will be monitored during their stay in ICU up to five days from the first blood culture i.e. to the time of the final blood culture report. On the first day two blood samples will be taken for culture. One is managed as a routine blood culture in the main laboratory. The other is incubated for the Cognitor© Minus test. The blood culture bottles collected for the Cognitor© Minus test will be handled and incubated with the routine blood culture bottles. If there is bacterial growth in either of these blood cultures, the blood will be analysed to identify the organism(s) and the results made available for clinical management.

After 24 and 48 hours, the intensive care consultant is asked if the result of the test had indicated no bacteria in the original blood culture would he/she have discontinued antibiotics.

Intervention Type
Other

Primary outcome measure
Whether the clinician’s decision on continuing antibiotic would have been affected by the test result if it had been available is assessed through clinician interviews at 24 and 48 hours.

Secondary outcome measures
Number of defined daily doses of antibiotic that would have been saved if the clinician had decided to stop antibiotics upon receiving a negative test result is determined by reviewing the patient’s current antibiotic treatment and expected duration at 24 or 48 hours.

Overall study start date

07/01/2016

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Patient has blood culture taken in critical care unit
2. Age >18 years
3. Not palliative treatment
4. Discharge expected within 48 hours
5. Death not imminent
6. Blood culture positive <12 hours
7. Test cannot be completed on the day sample taken

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
1. Patient < 18 years of age
2. The treatment intent is palliative; the clinician is not committed to aggressive treatment
3. Treating clinician expects the patient to be discharged from the ICU on the day of evaluation (i.e. assessment for inclusion) or the following day
4. Death is deemed imminent and inevitable

Date of first enrolment
15/11/2016

Date of final enrolment
30/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospital
235 Euston Road
Fitzrovia
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

Sponsor details
250 Euston Road
London
England
United Kingdom
NW1 2PG

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Industry

Funder Name
Momentum Bioscience Ltd

Results and Publications

Publication and dissemination plan
The results will be published in peer reviewed journals and presented at national and international conferences. Results will also be disseminated via patient groups.

Intention to publish date
30/07/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No