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A prospective randomised, multicentre trial to assess the impact of laboratory based rapid diagnosis on outcome in patients with Blood Stream Infections

Submission date
25/10/2013

Registration date
25/10/2013

Last Edited
21/12/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[_] Results

[_] Individual participant data

[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Blood stream infections (BSI) are a major problem and about 8% of hospital inpatients have a BSI. Some will be admitted with a BSI and others will develop an infection during their hospital stay. Recent improvements in infection control have reduced the number of patients that acquire an infection during their hospital stay, but BSI still occur. In certain infections the death rate can be as high as 50% and every patient that contracts an infection has a longer hospital stay. BSI are diagnosed by taking a blood sample from patients with a suspected infection. Antibiotic treatment begins within hours, but it takes several days to reach a definitive diagnosis and identify the correct antibiotic. The initial antibiotic selected will be a broad spectrum antibiotic, based on the clinician's judgment. However, until bacterial analysis is performed it is unknown if the correct antibiotic has been selected and there can be a time lag of up to 35 days before patients receive appropriate antibiotic therapy for their BSI. Use of the correct antibiotics has been shown to reduce death rates by up to 50% in some patient groups. This study will assess the impact of new technology designed to speed up laboratory diagnosis.

Who can participate?
Patients aged 18 and over, in hospital with a BSI.

What does the study involve?
Patients will be randomly allocated into two groups. One group will be tested using the current diagnostic approach and the other group will be tested with the current diagnostic approach and also the new rapid diagnostic technology.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Southmead Hospital (UK).

When is the study starting and how long is it expected to run for?
August 2012 to December2013.

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Margaret Stoddart
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11978

Study information

Scientific Title
A prospective randomised, multicentre trial to assess the impact of laboratory based rapid diagnosis on outcome in patients with Blood Stream Infections

Acronym
RAPIDO

Study objectives
The research is to find out whether more rapid identification of the pathogens involved in a blood stream infection can reduce the chance of dying in the 28days following infection.

It will also asses whether rapid identification results in:
1. Faster recovery

2. Shorter hospital stay
3. Shorter time before receiving the correct antibiotic
4. Differences in total antibiotic use
5. Differences in NHS costs and cost-effectiveness of acute care.

It will also assess whether differences in clinical outcomes are related to differences in the timing and appropriateness of antimicrobial therapy.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=11978

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/SW/003; First MREC approval date 20/03/2012

Study design
Randomised controlled interventional trial; Design type: Diagnosis

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Infection; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions
Once a positive blood culture has been identified patients meeting the inclusion criteria will be randomised 1:1 to receive conventional diagnosis or rapid diagnosis. A web-based randomisation system will be used.

In each site samples allocated to conventional diagnosis will follow the usual SOPs directing the process in the individual Trusts.

The rapid diagnostic platform in all five sites will be MALDI-TOF technology. Where a sample has been randomised to the rapid diagnostic arm some of the sample will be retained and follow the conventional diagnostic pathway as well.

MALDI is a soft ionization technique used in mass spectrometry, allowing the analysis of organisms which tend to be fragile and fragment when ionized by more conventional ionization methods. The ionization is triggered by a laser beam (normally a nitrogen laser). A matrix is used to protect the bacteria from being destroyed by direct laser beam and to facilitate vaporization and ionization. MALDI-TOF spectra can then used for the identification of microorganisms. A colony of the microbe in question is smeared directly on the sample target and overlaid with matrix. The mass spectra generated are analysed by dedicated software and compared with stored profiles. Species diagnosis by this procedure is much faster, more accurate and cheaper than other procedures based on immunological or biochemical tests.

Intervention Type

Other

Phase
Not Applicable

Primary outcome(s)
To assess the impact of laboratory based rapid diagnosis of Blood Stream Infections on 28-day all-cause mortality.

Key secondary outcome(s))
1. To assess the impact of rapid diagnosis on all-cause mortality at 7 days
2. To assess the impact of rapid diagnosis on resolution of infection, measured by temperature
3. To assess the impact of rapid diagnosis on patient length of stay (days)
4. To assess the impact of rapid diagnosis on acquisition of Clostridium difficile infection within 28 days
5. To assess the impact of rapid diagnosis on in-hospital antibiotic consumption in the first 7 days
6. To assess the impact of rapid diagnosis on the NHS costs and cost-effectiveness of acute care
7. To assess the impact of rapid diagnosis on time to initiation of appropriate antibiotic therapy and time to appropriate de-escalation of empirical broad-spectrum antibiotic therapy
8. To investigate the relationship between the timing of appropriate antibiotic therapy and clinical outcomes

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Age 18 years and over
2. Male and female
3. Blood culture positive for bacteria or fungi
4. Admitted to hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Less than 18 years of age
2. Patients on the end of life pathway when the blood sample was taken
3. Previously randomised for this study as each patient will only be recruited once
4. Prisoners or young offenders in the custody of HM Prison Service in England or Wales.
5. Patients not recieving NHS care
6. Attending physician deems patient unsuitable

Date of first enrolment
01/08/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust (UK)

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Programme Grants for Applied Research; Grant Codes: PGfAR RP-PG-0707-10043

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration