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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

**Recruitment status**
No longer recruiting

**Registration date**
25/10/2013

**Overall study status**
Completed

**Last Edited**
21/12/2017

**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

### Contact name
Dr Margaret Stoddart

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## 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 measure
To assess the impact of laboratory based rapid diagnosis of Blood Stream Infections on 28-day all-cause mortality.

### Secondary outcome measures
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

### Overall study start date
01/08/2012

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
UK Sample Size: 4536

### 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
England

United Kingdom

### Study participating centre
**Southmead Hospital**
Bristol
United Kingdom
BS10 5NB

## Sponsor information

### Organisation

North Bristol NHS Trust (UK)

### Sponsor details
Trust Headquarters
Beckspool Road
Frenchay
Bristol
England
United Kingdom
B16 1JE

### Sponsor type
Hospital/treatment centre

### Website
http://www.nbt.nhs.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

### 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