

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	☐ Prospectively registered
Registration date 25/10/2013	Overall study status Completed	☐ Protocol
Last Edited 21/12/2017	Condition category Infections and Infestations	☐ 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 December 2013.

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

Who is the main contact?
Dr Margaret Stoddart
Margaret.Stoddart@nbt.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Margaret Stoddart

Contact details
Department of Microbiology
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB
-
Margaret.Stoddart@nbt.nhs.uk

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 28 days following infection.

It will also assess 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

Primary study design

Interventional

Study design

Randomised controlled interventional trial; Design type: Diagnosis

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 be 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 receiving 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