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Molecular Diagnosis of Central Venous Catheter (CVC) associated infections

Submission date	Recruitment status	[X] Prospectively registered
25/11/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/12/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2022	Infections and Infestations	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-new-test-to-help-diagnose-infection-in-central-lines-for-children-and-young-people-having-cancer-treatment

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 03/39/13; N0484156267

Study information

Scientific Title
Molecular Diagnosis of Central Venous Catheter (CVC) associated infections

Acronym
MD-CVC

Study objectives
Central Venous Catheters (CVCs) are an essential part of the management of children undergoing treatment for cancer because they allow the safe administration of life-saving cancer drugs. Blood stream infection is a frequent and potentially serious complication of the use of CVCs. Some CVC associated infections can be treated by leaving the CVC where it is but frequently the best management involves taking the CVC out. Current methods of diagnosing CVC associated infection are unreliable with a result that more than 80% of CVCs removed for suspected infection are not in fact the source of infection. Also because of the difficulty in making a diagnosis, CVC associated infections may not be diagnosed or treated as early or as well as they can be.

In this study we will determine how best to use this test in children undergoing treatment for cancer and then find out if this new and relatively expensive test should be made available more widely.

In summary, we aim to find out whether the new test helps with the management of children with a central venous catheter, and improves the health outcomes.

Protocol can be found at http://www.hta.ac.uk/protocols/200300390013.pdf
More details can be found at http://www.hta.ac.uk/1449

Please note that, as of 27/08/2009, the anticipated end date of this trial has been updated from 30/11/2008 to 30/09/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics information provided at time of registration.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Central Venous Catheter Associated Infections

Interventions
There are two parts to the study:

In part one, we will determine how a novel molecular test for the diagnosis of CVC-associated infections performs in children being treated for cancer.

In the second part, we will determine the impact of the test as an adjunct to standard care on CVC management. Patients will be randomised to availability of the test plus standard care or standard care only.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
CVC survival

Secondary outcome measures
1. Duration of antibiotic treatment and hospitalisation for fever
2. Mortality
3. Economic analysis

Overall study start date
01/06/2005

Completion date
30/09/2009

Eligibility

Key inclusion criteria
1. Child, adolescent or young adult aged zero 18 years inclusive
2. Undergoing treatment for cancer/leukaemia or severe haematological disorders at a collaborating United Kingdom Children's Cancer Study Group (UKCCSG) centre
3. The routine standard of care requires a tunnelled single, double or triple lumen CVC or implanted vascular port
4. It is expected that the CVC or port will be required for a minimum of three months
5. Patients who already have an indwelling vascular access device in situ at the time of

recruitment are eligible if they have been apyrexial and have not received intravenous antimicrobial therapy in the preceding two weeks
6. Written informed consent has been obtained from the parent/guardian and assent from the patient where appropriate
7. National/Local Ethical Committee approval has been obtained

Participant type(s)
Patient

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
330

Key exclusion criteria
1. Failure to meet the above criteria
2. Patients with untunnelled CVCs or short term CVCs will not be included

Date of first enrolment
01/06/2005

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Microbiology
London
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Sponsor information

Organisation
Department of Health (UK)

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2011		Yes	No
Plain English results			26/10/2022	No	Yes