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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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Quarry House
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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 |