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CATCH - CATheter Infections in CHildren

Submission date	Recruitment status	[X] Prospectively registered
10/08/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/08/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2019	Other	

Plain English summary of protocol

Background and study aims
Most children admitted to paediatric intensive care units (PICU) need to have medicines given to them into their veins using a narrow tube, so they do not need repeated injections. This tube is called a central venous catheter. Occasionally these catheters can cause infections in the blood and sometimes the tubes can get blocked by small blood clots. Some intensive care units already use antibiotic or heparin coated catheters. Heparin is a medicine that can stop blood from clotting and might stop the tubes getting blocked. Antibiotics can be used to kill the bacteria which cause the infections. However, there is no proof that these coated catheters are better than the standard ones at preventing infections. Most of the PICUs in this country use standard lines. The only way to find out for certain is to compare children who are given antibiotic or heparin coated catheters with those who are given standard ones. The aim of this study is to see how three types of catheters compare at reducing the amount of blood infections in children. We will also look at the costs involved.

Who can participate?
Children less than 16 years of age who are admitted to an intensive care unit participating in the study and require insertion of a central venous catheter for at least 3 days.

What does the study involve?
Because we do not know which type of catheter is best, the type of catheter each child receives in the study is decided randomly by chance. Each child in the study has the same chance of getting any of these three catheters: a standard central venous catheter (not coated), a heparin-coated central venous catheter, or an antibiotic-coated central venous catheter.

What are the possible benefits and risks of participating?
We hope that the information we get from this study will guide policy about purchasing coated central venous catheters across the NHS and thereby improve treatment for children in the future.

Where is the study run from?
University College London - Institute of Child Health (UK)

When is the study starting and how long is it expected to run for?
September 2010 to March 2013

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof. Ruth Gilbert
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Study website
http://www.catchtrial.org.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01029717

Secondary identifying numbers
HTA 08/13/47; 08EB20

Study information

Scientific Title
A randomised controlled trial comparing the effectiveness of heparin bonded or antibiotic impregnated central venous catheters (CVCs) with standard CVCs for the prevention of hospital acquired blood stream infection in children

Acronym
CATCH

Study objectives
To determine the effectiveness of heparin bonded or antibiotic impregnated CVCs compared with standard CVCs for preventing hospital acquired blood stream infection.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/081347
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0015/52206/PRO-08-13-47.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Medical Research Ethics Committee (MREC), 19/02/2010, ref: 09/H0206/69

Study design
Multicentre three-arm double-blind (patients and PICU staff) randomised active controlled trial. Unblinded to randomising/inserting clinician

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Children in Paediatric Intensive Care

Interventions
Ratio of 1:1:1
1. Standard polyurethane Central Venous Catheter,
2. Antibiotic impregnated polyurethane CVC (minocycline and rifampicin)
3. Heparin bonded polyurethane CVC

All CVCs used in the trial are CE marked medical devices used for their intended purpose.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Time to first blood stream infection defined by a positive blood culture from a sample that was clinically indicated and taken more than 48 hours after CVC insertion and up to 48 hours after CVC removal

Secondary outcome measures
1. Rate of blood stream infection during CVC insertion per 1000 CVC days
2. Time to CVC thrombosis defined clinically
3. Time to a composite measure of blood stream infection based on the primary outcome or high bacterial DNA load or culture negative bloodstream infection based on clinical criteria
4. Mortality by 30 days
5. Type of bacteria and fungi isolated from positive blood cultures
6. Resistance to minocycline or rifampicin of blood culture or CVC tip isolate
7. Unexplained thrombocytopenia after insertion of CVC detected by routine laboratory monitoring
8. Time to randomised CVC removal
9. Length of stay requiring PICU
10. Total length of hospital stay for current episode (for up to 6 month post randomisation)
11. Cost effectiveness of heparin bonded vs. antibiotic impregnated vs. standard CVCs

Overall study start date
01/09/2010

Completion date
01/03/2013

Eligibility

Key inclusion criteria
1. Less than 16 years of age
2. Admitted to or being prepared for admission to an intensive care unit participating in the trial
3. Requires insertion of a central venous catheter
4. Requires one of the central venous catheter sizes available to the trial
5. Expected to require a central venous catheter for at least 3 days

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
1200

Key exclusion criteria
1. Previously enrolled in the CATCH trial
2. Has a known allergy or hypersensitivity to tetracyclines (including minocycline), rifampicin or heparin?
3. Patient known to be pregnant
4. Patient known to have a history of heparin induced thrombocytopenia
5. Patient is in a randomised controlled trial that excludes participation in CATCH

Date of first enrolment
01/09/2010

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London - Institute of Child Health
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
Institute of Child Health (UK)

Sponsor details
University College London
30 Guildford Street
London
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Sponsor type
Research organisation

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme (ref: 08/13/47)

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
01/03/2016

Individual participant data (IPD) sharing plan

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	23/04/2016		Yes	No
Other publications	post-hoc analysis of thrombosis risk	28/03/2019	18/12/2019	Yes	No