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PREVAIL study - PREVenting infection using Antimicrobial Impregnated Long lines

Submission date 13/11/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/11/2014	**Overall study status** Completed	
Last Edited 02/05/2019	**Condition category** Neonatal Diseases	

Plain English summary of protocol

Background and study aims
A peripherally inserted central catheter (PICC) is a long, thin tube that goes into a vein in the upper arm. Babies in neonatal units often need to take medicines and fluids through PICCs for a long time. PICCs are inserted in order to avoid the need for repeated painful procedures and can stay in place for several weeks. However, very occasionally these PICCs can cause infections in the blood. There are currently two types of PICCs available. One type is coated with an antibiotic and an antifungal which might prevent infection by killing bacteria (AM-PICC), and the other type is not (a standard PICC). Although both are available, currently hospitals tend to use the standard PICC (S-PICC). We are currently investigating antimicrobial catheters in children, however, we also need to find out which catheter (PICC) is better in babies or if there is no difference between them. The study will help hospitals to decide which type of PICC to use for babies admitted to neonatal intensive care in the future.

Who can participate?
Babies who require the narrowest PICC.

What does the study involve?
Participating babies will be randomly allocated to be treated with either an AM-PICC or a S-PICC. The study will follow your baby using routine records and will use infection results from samples that need to be taken as part of your baby's routine clinical care. When your baby's PICC is removed, we will also test the tip for bacteria. Information will also be collected from the babies' hospital admission up till 6 months after they have entered the study.

What are the possible benefits and risks of participating?
Both PICCs are CE marked for use in babies which means they comply with EU legislation. Currently normal practise in hospitals is to use the standard PICCs; however, there is no evidence to support that these are better or worse than AM-PICC. For all PICCs there is a small risk that they may become infected and cause an infection in the blood. By using the antimicrobial PICCs this risk of infection may decrease. As the antimicrobial PICCs do contain a tiny amount of antibiotic and antifungal, there is a potential that instead of being beneficial they could be problematic. However, the main foreseeable disadvantage, that bacteria/fungi might become resistant to the antibiotic/antifungal, is very unlikely indeed to have any impact on a baby's care.

Where is the study run from?
The study will be run from 18 neonatal units in the UK. The lead centre will be Bradford Teaching Hospitals NHS Foundation Trust. The study will be co-ordinated through the Medicines for Children Clinical Trials Unit, University of Liverpool.

When is the study starting and how long is it expected to run for?
The study will run from December 2014 until August 2017.

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

Who is the main contact?
Professor Ruth Gilbert and Dr Sam Oddie
prevail@liverpool.ac.uk

Study website
http://prevailtrial.org.uk/

Contact information

Type(s)
Scientific

Contact name
Prof Ruth Gilbert

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/167/02; 12EB13

Study information

Scientific Title

An unblinded, two-arm randomised controlled trial to determine the effectiveness and cost-effectiveness of antimicrobial impregnated (with rifampicin and miconazole) long lines (termed peripherally inserted central venous catheters, or AM-PICC) compared with standard PICC (S-PICC) for reducing blood stream infection (BSI)

Acronym
PREVAIL

Study objectives
The overall aim of the study is to determine whether AM-PICC should be introduced across the NHS for preterm babies. In very preterm infants, does the use of antimicrobial impregnated PICC, compared to standard PICC, reduce blood stream infection and is it cost effective?

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1216702

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee -Yorkshire & The Humber - Sheffield, 31/10/2014, Ref: 14/YH/1202

Study design
Unblinded two-arm randomised controlled trial

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
Infectious disease, preterm babies requiring a PICC

Interventions
1. Antimicrobial impregnated (with rifampicin and miconazole) peripherally inserted central venous catheters (AM-PICC)
2. Standard PICC (S-PICC)

Intervention Type
Device

Primary outcome measure

Time to first blood stream infection based on a positive blood culture (including fungal BSI) taken between 24 hours after randomisation until 48 hours after removal.

As part of the primary endpoint there will be two sensitivity analyses:
1. A sensitivity analysis confined to clinically serious BSI defined by positive culture and the baby is treated for more than 72 hours with intravenous antibiotics or dies during treatment
2. Time to first BSI based on a positive blood culture (including fungal BSI) taken between 24 hours after PICC insertion until 48 hours after removal

Secondary outcome measures
1. Rifampicin or miconazole resistance in any isolate from blood culture
2. Rifampicin or miconazole resistance in any isolate from PICC tips
3. Death within 6 months of randomisation
4. Death before discharge
5. Rate of BSI per 1000 PICC-days (including recurrent BSI)
6. Rate of one or more BSI
7. Rate of catheter-related BSI
8. Time to a composite measure of BSI including culture-negative BSI (based on reason for antibiotic treatment beyond 72 hours after a negative blood culture sample)
9. Rate of blood culture sampling per 1000 PICC days
10. Duration of antimicrobial exposure from randomisation up to 48 hours after line removal
11. Rate of chronic lung disease 36 weeks postmenstrual age
12. Rate of necrotizing enterocolitis (NEC): Bells stage II or III
13. Rate for treatment for retinopathy of prematurity before NNU discharge
14. Rate of abnormalities on cranial ultrasound
15. Time to full milk feeds after randomisation
16. Breast milk intake at discharge from NNU
17. Total duration of parenteral nutrition from randomisation until discharge from NNU
18. Time to PICC removal

Overall study start date
01/12/2014

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. Babies who require a PICC (Premicath 1 Fr)
2. Admitted to a NNU that is recruiting for this trial
3. Parent/legal representative of the baby gives informed written consent for the trial

Note: Babies with the following can be included in the trial:
1. Congenital malformations
2. Gastrointestinal surgical conditions
3. Previous PICC (non-trial PICC)
4. Previously treated BSI which has resolved in the opinion of the Investigator

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
858

Total final enrolment
861

Key exclusion criteria
1. Baby has been previously entered into this trial
2. Baby has a known allergy or hypersensitivity to rifampicin or miconazole

Date of first enrolment
01/06/2015

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Women's Hospital
Birmingham
United Kingdom
B15 2TG

Study participating centre
Bradford Royal Infirmary
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Homerton Hospital
London

United Kingdom
E9 6SR

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Study participating centre
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Study participating centre
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Study participating centre
Liverpool Women's Hospital
Liverpool
United Kingdom
L8 7SS

Study participating centre
Newham University Hospital
Plaistow
United Kingdom
E13 8SL

Study participating centre
Nottingham City Hospital
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Nottingham University Hospital (QMC)
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Queen's Hospital
Romford
United Kingdom
RM7 0AG

Study participating centre
Royal Bolton Hospital
Bolton
United Kingdom
BL4 0JR

Study participating centre
Royal Oldham Hospital
Oldham
United Kingdom
OL1 2JH

Study participating centre
Royal Preston Hospital
Preston
United Kingdom
PR2 9HT

Study participating centre
St Mary's Hospital
Manchester
United Kingdom
M13 0JH

Study participating centre

St Michael's Hospital
Bristol
United Kingdom
BS2 8EG

Study participating centre
The Jessop Wing
Sheffield
United Kingdom
S10 2SF

Study participating centre
The Royal London Hospital
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust (UK)

Sponsor details
c/o Emma Pendleton
Joint Research & Development Office
Division of Research & Innovation
Great Ormond Street Hospital for Children NHS Foundation Trust
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	02/05/2019	Yes	No
HRA research summary			28/06/2023	No	No