

PREVAIL study - PREVenting infection using Antimicrobial Impregnated Long lines

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

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

Contact information

Type(s)

Scientific

Contact name

Prof Ruth Gilbert

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Unblinded two-arm randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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**

United Kingdom

England

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)

ROR

<https://ror.org/03zydm450>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes