ISRCTN82571474 https://doi.org/10.1186/ISRCTN82571474

Skin antiseptic trial for insertion of central venous catheters in neonates

Submission date
07/07/2016

Recruitment status
No longer recruiting

Registration date
14/07/2016

Overall study status
Completed

Last Edited
01/11/2023

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
When in intensive care, many premature babies need to have a special catheter (thin tube) put into one of their larger (central) veins to give liquid nutrition safely to help them grow (percutaneous central venous catheter, PCVC). These catheters are vital, but can sometimes become infected. Catheter infection is a dangerous complication. Cleaning a baby's skin with antiseptic before inserting a catheter is one important way to prevent catheter infection. Some antiseptics may be better at preventing catheter infection than others, as well as being safer to use on the thin vulnerable skin of premature babies. Doctors don't yet know which antiseptics are safest and best to use in premature babies. It is therefore important to find out which antiseptics are best for use in premature babies. Chorhexidine and alcohol and two different antiseptics that are commonly used in neonatal units to clean the skin of babies before catheters are inserted. Sometimes these particular antiseptics are used individually and sometimes they are used in combination. In the future a large study will be conducted to compare two forms of these antiseptics for cleaning the skin in premature babies, to find out if chlorhexidine on its own is just as good at cleaning a baby's skin as chlorhexidine mixed with alcohol. The findings will guide doctors in deciding which antiseptic to choose for skin preparation in premature babies and will show if alcohol is important to use along with chlorhexidine, or whether alcohol can be avoided. The aim of this study is to investigate whether a large scale study looking at the effectiveness and safety of these antiseptic solutions for cleaning skin before PCVC insertion is feasible.

Who can participate?
Premature babies born at least six weeks early who need a PCVC placed as part of their routine care.

What does the study involve?
Babies in the study are randomly allocated to one of two groups, who each have the skin cleaned with one of two antiseptics just before the catheter is inserted and again just before the catheter gets removed. Three quarters of the babies are randomly allocated to receive an chlorhexidine mixed with alcohol (70% isopropyl alcohol-based 2% chlorhexidine gluconate) and one quarter to receive chlorhexidine antiseptic (2% chlorhexidine gluconate). The skin and the catheters are tested after removal to see if they ended up coated with (colonised by) bacteria by

the time of catheter removal, because catheter colonisation is a known major risk factor for infection. The number of babies recruited to the study and who stayed in until the end of the study are also recorded to gather information about how many babies are needed to conduct a larger study.

What are the possible benefits and risks of participating?
It is not known whether there will be any benefits of taking part in this study, however if the antiseptic the participants receive is more effective than the one normally used for central venous catheter insertion, then they may benefit from a decreased risk of catheter infection. Both antiseptic solutions chosen for use in this study are already commonly used in premature babies in Europe and America. Skin reactions such as redness and chemical burns have occasionally been reported with both of these antiseptics. The risk of skin reactions is increased when excess antiseptic solution is used or when it is in prolonged contact with the skin in very premature babies.

Where is the study run from?
Norfolk and Norwich University Hospital, Norwich (lead centre) and Medway Maritime Hospital, Gillingham (UK)

When is the study starting and how long is it expected to run for?
May 2015 to March 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Paul Clarke (scientific)
paul.clarke@nnuh.nhs.uk
2. Mrs Tracy Oliver (public)
tracy.oliver@nnuh.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Paul Clarke

ORCID ID
https://orcid.org/0000-0001-6203-7632

Contact details
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
United Kingdom
NR4 7UY
+44 1603 286342
paul.clarke@nnuh.nhs.uk

Type(s)
Public

Contact name
Mrs Tracy Oliver

Contact details
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
United Kingdom
NR4 7UY
+44 1603 288530
tracy.oliver@nnuh.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2015-000874-36

Protocol serial number
19899

Study information

Scientific Title
The efficacy and safety of two topical antiseptic solutions for skin disinfection prior to percutaneous central venous catheter insertion in preterm neonates: a feasibility study

Acronym
ARCTIC

Study objectives
The aim of this study is to investigate the feasibility of conducting a full scale trial of the efficacy and safety of two topical antiseptic solutions for skin disinfection prior to percutaneous central venous catheter insertion in preterm neonates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge South Research Ethics Committee, 30/10/2015, ref: 15/EE/0345

Study design
Randomised; Interventional; Design type: Treatment, Diagnosis, Prevention, Process of Care, Drug, Management of Care, Active Monitoring

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Children, Primary sub-specialty: Neonatal

Interventions
Preterm infants born at <34 weeks' gestation who are undergoing planned insertion of a percutaneously-inserted central venous catheter will be randomised to receive one of two commonly used topical disinfection agents for skin antisepsis: aqueous-based 2% chlorhexidine gluconate (2%CHG), or 70% isopropyl alcohol-based 2% chlorhexidine gluconate (70%IPA/2% CHG). The interventional antiseptic for skin disinfection will be used at the time of catheter insertion and also at removal. For both arms, follow up will proceed from catheter insertion up until 48 hours post catheter removal. Randomisation will use a web-based facility and a stratified block randomisation method to stratify groups by birth gestation and within neonatal centre. Randomisation will provide a 3:1 allocation ratio in favour of the alcohol-based antiseptic.

Follow up of study participants involves daily assessment of skin integrity of the catheter insertion site, daily evaluation of sepsis, and recording of concomitant antibiotics/antifungals until 48 hours post catheter removal. At catheter removal one exit-site skin swab and two catheter segments (proximal portion and a catheter tip portion) will be obtained and will be sent for microbiological culture.

Intervention Type
Other

Primary outcome(s)
Proportion of babies in the 70%IPA/2%CHG arm with catheter colonisation as determined by culture of catheter segments taken at the time of catheter removal.

Key secondary outcome(s))
1. Rates of recruitment and retention to the study and factors affecting these are determined by proportions of eligible patients enrolled and proportion of enrolled subjects completing the study, and collection of the views of parents and clinicians on factors affecting recruitment and retention
2. Proportion of infants with positive exit-site skin swabs are measured by microbiological culture of catheter segments taken at catheter removal
3. Number and type of catheter segments culture positive are measured by microbiological culture of the catheter segments (proximal portion and the tip portion) taken at catheter removal
4. Bacterial species (typed via molecular methods using Next Generation sequencing) of isolates identified on any positive blood culture obtained during the indwelling of the catheter and up until 48 hours post catheter removal, and any positive exit-site skin swab or positive catheter segment culture taken at the time of catheter removal
5. Proportion of infants undergoing an infection screen in the period between catheter insertion and 48 hours post-catheter removal that meets case definition for definite catheter-related sepsis
6. Proportion of infants with positive blood culture from any infection screen in the period between catheter insertion and 48 hours post-catheter removal that meets definition for catheter-associated sepsis
7. Proportion of infants completing study with complete data for the primary outcome and

proportions of infants with missing data collection forms
8. Daily skin morbidity scores are assessed using a validated neonatal skin condition scoring system in the period between catheter insertion and 48 hours post-catheter removal

Completion date
15/10/2019

Eligibility

Key inclusion criteria
1. Preterm infants born at <34 weeks' gestation
2. Requiring routine insertion of a PCVC for parenteral nutrition
3. No new suspected sepsis with commencement of antibiotics occurring within the 48 hours preceding planned catheter insertion
4. No other indwelling PCVC already in situ

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
116

Key exclusion criteria
1. No realistic prospect of survival in the short term
2. Life-threatening congenital abnormality
3. Underlying skin condition
4. Already has another indwelling PCVC in situ or was previously enrolled into the study in respect of an earlier PCVC episode
5. Positive blood culture (BC) within the past 7 days without a subsequent negative blood culture result
6. Antibiotic treatment commenced for suspected sepsis within the preceding 48 hours

Date of first enrolment
13/03/2017

Date of final enrolment
27/07/2018

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Norfolk and Norwich University Hospital
Neonatal Unit
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Sponsor information

Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/10/2023	01/11/2023	Yes	No
Protocol article	protocol	19/02/2019		Yes	No
Basic results		21/01/2020	10/11/2020	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	version 1.2	18/11/2016	30/08/2023	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes