SAFETY AND EFFICACY OF 2% CHLORHEXIDINE GLUCONATE (CHG) AQUEOUS VERSUS 2% CHG IN 70% ISOPROPYL ALCOHOL FOR SKIN DISINFECTION PRIOR TO PERCUTANEOUS CENTRAL VENOUS CATHETER INSERTION IN PRETERM NEONATES: THE ARCTIC FEASIBILITY RANDOMISED CONTROLLED TRIAL

ARCTIC
Antiseptic Randomised Controlled Trial for Insertion of Catheters

@ARCTIC_Trial

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Background & Aim:

- Catheter-related sepsis remains a significant threat to preterm babies in the neonatal intensive care unit (NICU)
- Evidence is lacking about the optimal skin disinfection to be used for catheterisation in preterm infants
- We aimed to conduct a feasibility study to inform the design of a definitive randomised controlled trial (RCT) to investigate the safety and efficacy of alcohol-based vs. aqueous-based 2% Chlorhexidine Gluconate (CHG) antiseptic formulations for skin disinfection prior to percutaneous central venous catheter (PCVC) insertion

Methods:

- We conducted a masked feasibility RCT in two tertiary-level neonatal intensive care units (ISRCTN: 82571474)
- We randomised infants born <34 weeks' gestation, and due to undergo PCVC insertion, to receive in a 3:1 ratio either 2%CHG-70% isopropyl alcohol (IPA) or 2%CHG-aqueous for skin antisepsis prior to catheter insertion
- Our feasibility study outcomes included rates of: i) recruitment and retention; ii) data completeness; iii) catheter colonisation, catheter-related sepsis (CRS), catheter- associated sepsis (CAS), and CRS/CAS per 1,000 PCVC days. Safety outcomes were daily skin morbidity scored using a validated neonatal skin scoring system, and recorded from catheter insertion until 48h post-removal
- Primary clinical outcome was the proportion of infants in the 2%CHG-70%IPA arm with catheter colonisation at the time of catheter removal. Target sample size was at least 93 infants with successful PCVC insertion based upon an anticipated 20% incidence of PCVC colonisation in the reference 2%CHG-70%IPA group (estimated with 95% confidence interval (CI) 11% to 31%)
- The Trial Protocol http://www/npeu.ox.ac.uk/arctic and further details of the methodology are published [1]

Results:

- 116 (65.2%) of 178 eligible infants were recruited and randomised. 88 (76%) were allocated to 2%CHG-70%IPA group
- Overall, 51.7% were boys, median (IQR) gestation at birth was 28 (26-30) wks, and median (IQR) age at catheterisation was 5 days (2-7 days); 40% catheters were inserted <3 days postnatal and 22% insertions were in babies <26 weeks GA. Postnatal age at catheter removal was on median day 14 (IQR: 10-20 days).
- 97 (84.1%) included infants completed the study. Rates of recruitment, retention and data completeness were good
- Primary outcome incidence was 4.1% (95% CI: 0.9%, 11.5%); overall catheter colonisation rate was 5.2% (5/97); CRS 2.3/1,000 catheter days; CAS 14.8/1,000 catheter days **(Table)**
- No significant antiseptic-related skin injury was reported

Table: Primary and secondary outcomes: bacteriology and sepsis

	70%IPA/ 2%CHG (n = 79)	2%CHG aqueous (n = 27)	All (n = 106)
Positive exit-site skin swab at catheter removal (before disinfection), n (%)	11 (15.1)	4 (16.7)	15 (15.5)
Missing	6	3	9
Positive exit site skin swab at catheter removal (after disinfection), n (%)	1 (1.4)	1 (4.3)	2 (2.1)
Missing	7	4	11
Culture positive catheter segments at removal, n (%)	**3 (4.1)***	2 (8.3)	5 (5.2)
Positive tip alone	1 (1.3)	1 (3.7)	2 (1.9)
Positive proximal segment alone	2 (2.5)	0	2 (1.9)
Both tip and proximal segment positive	0	1 (4.2)	1 (1.0)
Missing	6	3	9
Definite catheter-related sepsis, n (%)	1 (1.5)	1 (4.5)	2 (2.3)
Missing	13	5	18
Catheter-associated sepsis, n (%)	10 (13.7)	3 (12.5)	13 (13.4)
Missing	6	3	9
Total number of PCVC days	653	223	876
Definite catheter-related sepsis, n (rate per 1000 PCVC days)	1 (1.5)	1 (4.5)	2 (2.3)
Catheter-associated sepsis, n (rate per 1000 PCVC days)	10 (15.3)	3 (13.5)	13 (14.8)

***Primary outcome**

Conclusions:

- **The ARCTIC study provides preliminary reassurance regarding safe use of 2%CHG aqueous and 2%CHG-70%IPA in preterm neonates for skin disinfection prior to percutaneous central venous catheterisation**
- **A definitive trial is feasible, but the very low catheter colonisation rate in the reference 2%CHG-70%IPA group indicates that a very large sample size would be required (approx. 3,500 babies for a non inferiority trial)**

Reference: [1]. Clarke P, et al. *BMJ Open* 2019;9:e028022. Available open access 👉 bit.ly/3iBszQt

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