Implementation of a children’s hospital-wide central venous catheter insertion and maintenance bundle.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28671

Source
Nationaal Trial Register

Brief title
ICVC

Health condition

bloodstream infection, central venous catheter, prevention, children’s hospital, implementation, education

Sponsors and support

Primary sponsor: University Medical Center Rotterdam, Erasmus MC-Sophia Children's Hospital
Source(s) of monetary or material Support: Erasmus MC-Sophia Children's Hospital

Intervention

Outcome measures

Primary outcome

Primary outcome measure is the number of catheter-associated infections per 1000 line-

days.

Secondary outcome

The process outcome is degree of adherence to use of these CVC bundles. A cost-effectiveness analysis is part of the study.

Study description

Background summary

Background:

Catheter-associated bloodstream infections in children with central venous catheters (CVC) are an increasingly recognized serious safety problem worldwide, but are often preventable. CVC bundles proved effective to prevent infections in studies performed in single or multiple units. Successful implementation requires changes in the hospital system as well as behavioural changes of healthcare professionals. The aim of the study is to evaluate the process and the outcome of the implementation of a state-of-the-art CVC insertion and maintenance bundle throughout a large university children's hospital over an 18 month period.

Methods/ design:

An interrupted time series design will be used; the study will encompass all children who need a CVC. New state-of-the-art CVC bundles will be developed. The Pronovost-model will guide the implementation process. We developed a tailored multifaceted implementation strategy consisting of reminders, feedback, management support, local opinion leaders, and education. Primary outcome measure is the number of catheter-associated infections per 1000 line-days. The process outcome is degree of adherence to use of these CVC bundles. A cost-effectiveness analysis is part of the study. Outcomes will be monitored during three periods: baseline, pre-intervention, and post-intervention for over 18 months.

Discussion:

By applying an implementation model we will explore the challenges of implementing a hospital-wide safety program. This work will add to the body of knowledge in the field of implementation. We postulate that healthcare workers' willingness to shift from providing habitual care to state-of-the-art care may reflect the need for consistent care improvement.

Study objective

We will test the following hypothesis: implementation of hospital-wide CVC insertion and maintenance bundles on the guidance of the Pronovost-model promotes adherence to its use and reduces the number of CA-BSIs.

Study design

Outcomes will be monitored during three periods: baseline, pre-intervention, and post-intervention for over 18 months.

Intervention

The implementation of an Quality Improvement (QI) program. This QI will affect healthcare workers in care for CVC's.

QI program (a tailored multifaceted implementation strategy) consisted of: Reminders, feedback on performance, management support, local opinion leaders, and education.

Contacts

Public
Wytemaweg 80
Onno K. Helder
Rotterdam
The Netherlands
+31 (0)10 7037455
Scientific
Wytemaweg 80
Onno K. Helder
Rotterdam
The Netherlands
+31 (0)10 7037455

Eligibility criteria

Inclusion criteria

All healthcare workers employed at the Erasmus MC-Sophia Children's Hospitial, Rotterdam, involved in patient care will participate.

Exclusion criteria

Healthcare workers who are not involved in patient care.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	12840
Type:	Actual

Ethics review

Positive opinion

Date:	20-09-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3489
NTR-old	NTR3635
Other	METC ErasmusMC : 2012-375
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

1: Buijs EA, Zwiers AJ, Ista E, Tibboel D, de Wildt SN. Biomarkers and clinical tools in critically ill children: are we heading toward tailored drug therapy? Biomark Med. 2012 Jun;6(3):239-57. PubMed PMID: 22731898.
2: van Dijk M, Knoester H, van Beusekom BS, Ista E. Screening pediatric delirium with an adapted version of the Sophia Observation withdrawal Symptoms scale (SOS). Intensive Care Med. 2012 Mar;38(3):531-2. Epub 2011 Dec 9. PubMed PMID: 22160276; PubMed Central PMCID: PMC3286512.
3: Ista E, Wildschut E, Tibboel D. Creating or preventing opioid addiction, finding the right dose. Pediatr Crit Care Med. 2011 Sep;12(5):590-2. PubMed PMID: 21897158.
4: Valkenburg AJ, Boerlage AA, Ista E, Duivenvoorden HJ, Tibboel D, van Dijk M. The COMFORT-behavior scale is useful to assess pain and distress in 0- to 3-year-old children with Down syndrome. Pain. 2011 Sep;152(9):2059-64. Epub 2011 Jun 2. PubMed PMID: 21640484.
5: Boerlage AA, Ista E, de Jong M, Tibboel D, van Dijk M. The COMFORT behavior scale: is a shorter observation period feasible?. Pediatr Crit Care Med. 2012 Mar;13(2):e124-5. PubMed PMID: 21499179.
6: Duyndam A, Ista E, Houmes RJ, van Driel B, Reiss I, Tibboel D. Invasive ventilation modes in children: a systematic review and meta-analysis. Crit Care. 2011;15(1):R24. Epub 2011 Jan 17. Review. PubMed PMID: 21241490; PubMed Central PMCID: PMC3222058.
7: Ista E, van Dijk M, Gischler S, de Leeuw M, Poley MJ, Tibboel D. Weaning of opioids and benzodiazepines at home after critical illness in infants: a cost-effective approach. J Opioid Manag. 2010 Jan-Feb;6(1):55-62. PubMed PMID: 20297615.
8: Ista E, de Hoog M, Tibboel D, van Dijk M. Implementation of standard sedation management in paediatric intensive care: effective and feasible? J Clin Nurs. 2009 Sep;18(17):2511-20. Epub 2009 Jul 8. PubMed PMID: 19619202.

9: Ista E, van Dijk M, de Hoog M, Tibboel D, Duivenvoorden HJ. Construction of the Sophia Observation withdrawal Symptoms-scale (SOS) for critically ill children. Intensive Care Med. 2009 Jun;35(6):1075-81. Epub 2009 Apr 15. PubMed PMID: 19367394.
10: Ista E, van der Voort E. Assessment of withdrawal symptoms in pediatric intensive care patients, a new future? Pediatr Crit Care Med. 2008 Nov;9(6):654-5. PubMed PMID: 18997597.
11: Ista E, van Dijk M, Gamel C, Tibboel D, de Hoog M. Withdrawal symptoms in critically ill children after long-term administration of sedatives and/or analgesics: a first evaluation. Crit Care Med. 2008 Aug;36(8):2427-32. PubMed PMID: 18596622.
12: Ista E, van Dijk M, Gamel C, Tibboel D, de Hoog M. Withdrawal symptoms in children after long-term administration of sedatives and/or analgesics: a literature review. "Assessment remains troublesome". Intensive Care Med. 2007 Aug;33(8):1396-406. Epub 2007 Jun 1. Review. PubMed PMID: 17541548.
13: Ista E, Joosten K. Nutritional assessment and enteral support of critically ill children. Crit Care Nurs Clin North Am. 2005 Dec;17(4):385-93, x. Review. PubMed PMID: 16344208.
14: Ista E, van Dijk M, Tibboel D, de Hoog M. Assessment of sedation levels in pediatric intensive care patients can be improved by using the COMFORT "behavior" scale. Pediatr Crit Care Med. 2005 Jan;6(1):58-63. PubMed PMID: 15636661.