The NEOCLOT study will evaluate the efficacy and safety of the new, national, neonatal CVC-thrombosis guideline. Furthermore, risk factors as well as long-term consequences of CVC-thrombosis will be analysed" Sol et al (2018).

Abstract:

BACKGROUND: In critically ill (preterm) neonates, central venous catheters (CVCs) are increasingly used for administration of medication or parenteral nutrition. A serious complication, however, is the development of catheter-related thrombosis (CVC-thrombosis), which may resolve by itself or cause severe complications. Due to lack of evidence,

management of neonatal CVC-thrombosis varies among neonatal intensive care units (NICUs). In the Netherlands an expert-based national management guideline has been developed which is implemented in all 10 NICUs in 2014.

METHODS: The NEOCLOT study is a multicentre prospective observational cohort study, including 150 preterm and term infants (0-6 months) admitted to one of the 10 NICUs, developing CVC-thrombosis. Patient characteristics, thrombosis characteristics, risk factors, treatment strategies and outcome measures will be collected in a web-based database. Management of CVC-thrombosis will be performed as recommended in the protocol. Violations of the protocol will be noted. Primary outcome measures are a composite efficacy outcome consisting of death due to CVC-thrombosis and recurrent thrombosis, and a safety outcome consisting of the incidence of major bleedings during therapy. Secondary outcomes include individual components of primary efficacy outcome, clinically relevant non-major and minor bleedings and the frequency of risk factors, protocol variations, residual thrombosis and post thrombotic syndrome.

DISCUSSION: The NEOCLOT study will evaluate the efficacy and safety of the new, national, neonatal CVC-thrombosis guideline. Furthermore, risk factors as well as long-term consequences of CVC-thrombosis will be analysed.

TRIAL REGISTRATION: Trial registration: Nederlands Trial Register NTR4336 . Registered 24 December 2013.

Full Text

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Sol, J.J., van de Loo, M., Boerma, M., Bergman, K.A., Donker, A.E., van der Hoeven, M.A.H.B.M., Hulzebos, C.V., Knol, R., Djien Liem, K., van Lingen, R.A., Lopriore, E., Suijker, M.H., Vijlbrief, D.C., Visser, R., Veening, M.A., van Weissenbruch, M.M. and van Ommen, C.H. (2018) NEOnatal Central-venous Line Observational study on Thrombosis (NEOCLOT):

evaluation of a national guideline on management of neonatal catheter-related thrombosis. BMC Pediatrics. 18(1), p.84.

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