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.


Reference: