



Use of In-Line Filtration in Critically Ill Children

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Background: Particulate contamination of infusion solutions and their systemic administration during infusion therapy has been linked to various clinical problems. It is well established that the pathophysiology of Multi-Organ Failure (MOV) involves deteriorations of the microcirculation and integrity of endothelial cells. As a consequence of this an imbalance between pro- and anticoagulatory factors may develop and microthrombi may form. Mediators like tissue factor (TF) and platelet activating factor (PAF) have been linked to the formation of microthrombi. Particles have been discussed as a causative agent for this syndrome by various authors. Their effect on morbidity and mortality of patients has however not yet been established. Particles may have additional harmful effects: Direct thrombogenesis by the particle material, damaging endothelial cells in the capillary network, embolisation of the pulmonary vasculature, acting as a crystallisation focus for the development of granuloma, promoting the formation of Giant Cells. Various authors have shown that the use of end line infusion filters significantly reduces the rate of thrombophlebitis. A recently published study also showed that the use of end line infusion filters significantly reduced the rate of overall complications in neonates. The purpose of this study is to determine whether the use of in-line filtration shows any effect on the outcome of sepsis, systemic inflammatory response syndrome (SIRS), thrombosis, or organ failure in critically ill children admitted to the pediatric intensive care unit (PICU).

Methods: This is a prospective, randomized, controlled, open, parallel assignment efficacy study. 800 patients (up to 18 years) admitted to the pediatric intensive care unit (PICU) are randomly assigned to one of the following groups: use of end line positively charged 0.2 μm and uncharged 1.2 μm infusion filters or control group. The primary outcome measure is the incidence of sepsis, thrombosis, SIRS and organ failure.

Principal investigator: Dr. Michael Sasse, Hannover Medical School, Germany

Status: Recruitment finalized, data under evaluation

Sponsor: Hannover Medical School

Register:

<http://www.clinicaltrials.gov/ct2/show/NCT00209768?term=NCT00209768&rank=1>