



Rate of Catheter Colonization and Risk of Bloodstream Infection During Use of Two Different Central Venous Catheters (CVC)

B. Braun Melsungen AG, Hospital Care, Clinical Development

Background: Central venous catheters are an essential part of patient management in the ICU (Intensive Care Unit). The use of these catheters is associated with infectious complications that are an important iatrogenic source of morbidity and mortality. Many catheters become colonized with bacteria but only a proportion of colonised catheters go on to cause bacteremia and sepsis. It is currently impossible to prospectively identify which of the catheters will become colonized and lead to sepsis. Various types of antiseptic or antimicrobial vascular catheter coatings have been developed. Studies showed that the coated catheters were effective in limiting the catheter colonization rate and that they may decrease the risk of catheter-related bloodstream infections. The "Certofix protect" was developed by B.Braun to reduce the risk of catheter related infections. It is a catheter with a modified surface that consists of a high molecular weight polymer which is non-covalently linked to the polyurethane catheter material. This clinical trial is performed to compare the safety and efficacy of the coated central venous catheter, Certofix® protect, with that of the non-coated standard catheter Certofix®.

Methods: This is a prospective, multi-center, parallel group, controlled, randomized, double-blind clinical study comparing two CE-marked central venous catheters. 680 patients are randomly assigned to one of the following treatment groups: non-coated standard catheter Certofix® or coated central venous catheter, Certofix® protect. The primary endpoints are the incidence of catheter colonization and the incidence of blood stream infections.

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Status: Finalized as planned, data under evaluation

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Register:

<http://www.clinicaltrials.gov/ct2/show/NCT00555282?term=NCT00555282&rank=1>