Universität Basel

Research Project

Chlorhexidine vs PVP iodine in alcohol for disinfection of the surgical site: a cluster-randomized multicenter trial Investigator initiated clinical trials (IICT)

Third-party funded project

Project title Chlorhexidine vs PVP iodine in alcohol for disinfection of the surgical site: a cluster-randomized multicenter trial Investigator initiated clinical trials (IICT)
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Surgical site infections (SSIs) are the most common nosocomial infections in surgical patients causing significant increases in morbidity, mortality, and health care costs. As they are usually caused by components of the normal skin flora disinfection of the surgical site with an antiseptic skin preparation is standard practice prior to any surgical intervention. To date, the Centers for Disease Control and Prevention (CDC) did not define any compound. However, the new WHO guideline favors chlorhexidine (CHX)-containing compounds based on two randomized controlled clinical trials (WHO-guideline, Lancet Infectious Diseases, in press 2017). The CDC recommends 2% CHX-based preparations for cleaning the insertion-site of vascular catheters. As compared with PVP-iodine (PI) CHX in alcoholic solution reduces catheter-related infections by roughly 50% suggesting that CHX solutions may also be superior to PI in preoperative skin antisepsis. The available evidence from 12 RCTs shows that for preoperative skin antisepsis alcoholic antiseptic solutions are more effective then aqueous ones in reducing SSI (OR 0.60; 95% CI: 0.45 - 0.78). Moreover, the available evidence from 5 RCTs shows that alcoholic PI is neither beneficial nor harmful in reducing SSI rate as compared to alcoholic CHX (OR 0.60; 95% CI: 0.25 - 1.46). A landmark paper by Darouiche (NEJM 2010) demonstrated disinfection with alcoholic CHX to be superior to PI to prepare the surgical site. However, whether the alcoholic compound or CHX was responsible for the improved outcome remained unclear. In 2016 Tuuli published data on superiority of alcoholic CHX to alcoholic PI in cesarean section. However, the SSI-rate was higher than in a very large observational study from our institution even if the same definitions and follow-up procedures were applied.The number of applications of disinfectants required for preoperative skin antisepsis is as of yet unresolved. The current practice of 3 applications is not based on sufficient evidence from large randomized clinical trials. Unpublished data from the University Hospital of Basel show that in approximately 10% of patients an adequate reduction of microbial counts on the incision site can only be achieved by 3 as compared to 2 paints.Therefore, a randomized controlled clinical trial is needed comparing the effect of CHX and PI in alcoholic solutions and after decades of use, the best disinfection compound will have been evaluated.Swissnoso - the association of Swiss infection control specialists - provides services for ANQ (Nationaler Verein für Qualitätsentwicklung in Spitälern und Kliniken) in terms of measuring incidence of SSIs on a large scale. Currently, more than 250'000 patients have been included to assess the rate of SSIs stratified by type of surgery and underlying diseases. A pilot study has started in 2015 to standardize preoperative measures to prevent SSIs, measures that are lacking in more than 50% of hospitals. The university hospitals of Basel, Zurich and Berne as participating centers in the trial

included altogether 3’420 patients in cardiothoracic and abdominal surgery in the aforementioned SSI-surveillance in 2104 and will therefore be able to provide the necessary case numbers.We will conduct a cluster-randomized multi-center trial. Outcome variable is SSIs, and non-inferiority defined as nonsignificant difference in the rate of SSIs among patients undergoing the similar procedure with >500 patients in each strata with a power of 90%. Sample size calculations - based on the meta-analysis to be published by WHO and the Darouiche study will ask for 500 patients in each group. We will include >1000 patients in 2 strata: abdominal surgery and cardiothoracic surgery, summing up to >2000 patients. The departments of surgery of the study sites will be randomized to use alcoholic CHX or alcoholic PVP iodine during a fixed time period, and after e.g. one month, switched over to the other product. Data will be collected by a case-report form. Data on SSI will be assessed by the Swissnoso surveillance system. A standard operating procedure for disinfection of the surgical site will be developed as there is NO national standard. A working group will be established to coordinate local principle investigators to monitor progress of the study, and guarantee compliance with the protocol.In addition, microbial swabs prior to and after each paint of the skin antisepsis will be taken in 250 patients in each stratum to measure relative reduction of bacterial counts on the insertion site. Adequate neutralization tests and state-of-the art swab techniques using eSwabs^{TM}will be used.After decades of use the best disinfection compound and necessary number of paints will be known.

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