Prevention of Surgical Site Infections in Emergency Colorectal Surgery: Design of a Multicenter Randomized Clinical Trial

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Abstract:
Surgical Site Infections (SSIs) account for 31% of all hospital acquired infections (HAIs). Pre-operative intravenous antibiotic delivery (IVAD) dramatically reduces the risk of SSI. The overall SSI rate is 1.9% in the U.S and at least 3 times higher in low-income countries. Tumescent Anesthesia Antibiotic Delivery (TAAD) involves a pre-operative subcutaneous infiltration, at the site of a proposed incision, of a relatively large volume (≥ liter or more) of a dilute solution of cefazolin (1gm), metronidazole (500mg), lidocaine (1gm) and epinephrine (1mg) in a liter bag of saline. The subcutaneous bioavailability (AUC area under the concentration-time curve within a given tissue) of cefazolin following TAAD, is 10 to 100 times that following intravenous antibiotic delivery. The trial will compare two modes of antibiotic delivery: Control: IVAD & Treatment: IVAD+TAAD. Retrospective data (Watanabe M, et al. Risk factors for surgical site infection in emergency colorectal surgery: a retrospective analysis. Surg Infect (Larchmt). 2014;15:256-61) suggests the risk of an SSI for contaminated-dirty emergency colorectal surgery is at least 30%. Assuming an effect size of treatment to be 50%, our estimated sample size is n=216. TAAD has been approved for an Investigative New Drug application (IND#127921) which will make it the first to be approved regarding subcutaneous injection of antibiotics.

Biography:
Jeffrey A. Klein graduated from UCR as a math major in 1967. His subsequent academic training included MS in math (UCSD ’70), MD (UCSF ’76), MPH (Biostatistics UC Berkeley ’77), American Board of Internal Medicine (UCLA 1977-1980), NIH Research Fellowship in Clinical Pharmacology (UCSF 1980-1981), American Board of Dermatology (UCI 1981-1984). Dr. Klein invented tumescent anesthesia, which has been cited in nearly 500 articles. He has authored 48 peer reviewed articles and he has 26 U.S. Patents, mostly associated with devices and methods related to tumescent anesthesia. Dr. Klein is a clinical professor of dermatology at UC Irvine where he has supported several UCR summer graduate seminars in biostatistics; he has a busy dermatology practice in San Juan Capistrano, and he is the president of HK Surgical, Inc., a medical device company that markets devices for tumescent anesthesia. His current research is focused on launching a multi-site randomized clinical trial involving the use of tumescent anesthesia antibiotic delivery (TAAD) for preventing incisional surgical site infections.