

PREPARE-Closed: A Pragmatic Randomized Trial Evaluating Preoperative Alcohol Skin Solutions in Closed Fractured Extremities

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Purpose: Several international guidelines recommend chlorhexidine-alcohol antiseptic skin preparation to prevent surgical site infection (SSI). However, newer iodine-alcohol based solutions claim longer and broader antimicrobial effectiveness. This trial compared the effectiveness of iodine-povacrylex in 74% alcohol versus 2% chlorhexidine gluconate in 70% alcohol for preventing surgical site infections in patients undergoing surgery for a closed lower extremity fracture.

Methods: We conducted this multiple period, cluster-randomized, crossover clinical trial at 23 hospitals in the US and Canada. All patients receiving surgical fixation for a closed lower extremity fracture were eligible for enrollment. Each participating site used its randomly allocated antiseptic solution for all eligible patients during the initial 2 months of recruitment. The sites then switched to the opposite antiseptic, alternating between the study solutions every two months. The primary outcome was SSI within 90 days, and the secondary outcome was unplanned fracture-related reoperation within 1 year.

Results: We enrolled 6863 patients and 6785 were included in the primary analysis. The mean age of the study participants was 54 years (standard deviation [SD] 20), and 51% were female. The mean ISS of the participants was 9 (SD 6). 38% of fractures occurred from a fall from standing height, and 30% occurred from a motor vehicle collision. The most common fractures were of the proximal femur (25%), distal tibia (25%), and the knee (19%). 27% of participants received intrawound topical antibiotics, and the median duration of perioperative intravenous antibiotics was 1.0 days (interquartile range 1.0). Primary outcome data are available for 6477 of 6785 patients (96%). Full data analysis and results will be ready for the late breaking deadline in August 2023.

Conclusion: This large multicenter clinical trial will definitively determine if the choice of alcohol antiseptic skin solution can decrease SSI and unplanned reoperations in patients with surgically treated closed lower extremity fractures.