

## **PREPARE-Open: A Pragmatic Randomized Trial Evaluating Preoperative Alcohol Skin Solutions in Open Fractured Extremities**

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**Purpose:** The previous Aqueous-PREP trial demonstrated similar effectiveness of povidone-iodine and chlorhexidine gluconate aqueous skin solutions for the prevention of open fracture infections. However, alcohol-based skin preparations are more commonly used and are believed to be more effective. The purpose of this trial is to compare the effectiveness of iodine-povacrylex in 74% alcohol versus 2% chlorhexidine gluconate (CHG) in 70% alcohol for the antiseptic skin preparation of open fracture surgery.

**Methods:** A multiple period, cluster-randomized, crossover clinical trial was conducted at 22 hospitals in the US and Canada. All patients receiving surgical fixation for an open extremity fracture were eligible for enrollment. Each participating site used their 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 2 months. Once enrolled, individual study participants received the same allocated solution for all of their planned surgical procedures. The primary outcome was surgical site infection (SSI) within 90 days, and the secondary outcome was unplanned fracture-related reoperation within 1 year.

**Results:** 1785 patients were enrolled and 1700 were included in the primary analysis. The mean age of the study participants was 45 years (standard deviation [SD] 18) and 64% were male. 39% of included fractures were Gustilo-Anderson Type IIIA injuries. Surface contamination was reported in 29% of the open wounds and 9% contained contamination embedded in the deep tissues. There were 805 open tibia fractures and 73% of all included fractures occurred in the lower extremity. Temporary fracture stabilization was used for 19% of the fractures. 35% of the fractures received intrawound topical antibiotics. The median duration of perioperative intravenous antibiotics was 3.0 days (interquartile range 2.0). Primary outcome data are available for 1651 of 1700 patients (97%). Full data analysis and results will be ready for the late-breaking deadline in August 2023.

**Conclusion:** Aqueous iodine and CHG solutions demonstrated similar effectiveness in a prior open fracture trial; however, it remains unknown if the more commonly used alcohol-based solutions achieve improved synergistic effectiveness. This large multicenter clinical trial will fill this remaining knowledge gap to determine if the choice of antiseptic skin solution can decrease SSI and unplanned reoperations for open fracture patients.