Statistical Analysis Plan (SAP)

Preadmission Skin Wipe Use for Surgical Site Infection Prophylaxis in Adult Orthopaedic Surgery Patients

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1. Introduction

The aim of this project was to assess in a single center randomized clinical trial (RCT) the use of the addition of 2 doses of 2% topical chlorhexidine gluconate wipes or topical TheraworxTM wipes to standard ChloroPrep skin preparation on patients undergoing orthopedic surgery procedures. Our objective is to test the hypothesis that administration of 2% topical chlorhexidine gluconate or topical TheraworxTM wipes (one dose the night before surgery and one on the day of surgery) will reduce the number of surgical site infections in patients undergoing orthopedic surgery procedures. Furthermore, we will explore whether the rate of surgical site infections from patients who utilized 2% topical chlorhexidine gluconate wipes significantly differs from those who utilized topical TheraworxTM wipes.

2. Study Design

This study is a randomized study that will include three groups: a control group, intervention group one that will be administered topical 2% chlorhexidine gluconate (CHG) wipes once the night before surgery and once on the day of surgery, and intervention group two that will be administered topical TheraworxTM wipes once the night before surgery and once on the day of surgery. After IRB is approved, 500 participants (160-180 per group) will be collected for the prospective study. Patients will be randomized into groups using a random number list generated in excel, which will be consulted by a research nurse or research fellow, who will instruct the patient in the use of the product related to their group assignment. Dr. Shah or Dr. Naranje will perform orthopedic surgery on the participants without knowledge of their group assignment. Patients will be assessed for regimen compliance by survey. At clinic visits, patients will be assessed for the presence of surgical site infection, wound healing and scar formation, pain scores, and will be asked to complete a self-administered patient satisfaction questionnaire.

Patients will be assessed for signs and symptoms of infection at their two-week, six-week, and three-month clinical visits. We will continue follow up for one year postoperatively and compare the infection rate among the three groups.

3. Aims and Objectives

To study if 2% topical chlorhexidine gluconate or topical TheraworxTM wipes night before will reduce the number of surgical site infections in patients undergoing orthopedic surgery procedures.

4. Outcomes

This section will present the outcomes investigated to answer the study aims and objectives. The analyses are described in section 6 Analyses.

4.1 Primary Outcome

Infection rate between the three study cohorts. Signs and symptoms of infection will be measured at the 2-week, 6-week, and 3-month visits.

4.2 Secondary Outcomes

- Patient compliance survey: Patients will be assessed for compliance on the morning of surgery.
- Visual assessment of wound healing and scar formation will be performed at each post-operative visit.
- Patients will be asked about any side effects regardless of intervention arm- the percentage of patients who report side effects, including rashes, irritation, or allergic reactions will be calculated for each intervention.

5. Populations to be Analyzed

Inclusion Criteria: deemed healthy enough for orthopedic surgery, age 18 and older, willing to comply with study protocol, and without clinical signs of skin infection.

Exclusion Criteria: previous allergic reaction or absolute contraindication to topical chlorhexidine gluconate or any other study product ingredient, dermatologic disorders around the surgical site, signs of other infections, age under 18, pregnancy.

Patients will be randomly placed into study cohort.

5.1 Populations

Control group: 160 patients who will receive only standard skin preparation prior to surgery.

Intervention group 1: 160 patients who will be administered 2% Chlorhexidine Gluconate wipes once on the night prior to surgery and once on the day of surgery in addition to standard skin preparation.

Intervention group 2: 180 patents who will be administered TheraworxTM wipes once on the night prior to surgery and once on the day of surgery in addition to standard skin preparation.

Intention-to-Treat

All randomized study subjects. This will be the primary population for analysis.

Per Protocol

All randomized study subjects completing the whole study period (complete cases). For a specific analysis, study subjects with missing data on any of the variables in the model will be excluded from the analysis.

6. Analyses

The primary analysis will compare intervention groups and their respected rate of infection between baseline, 2-weeks. 6-weeks, and 3 months using a linear mixed model. Difference in infection rate from baseline to time points where it is measured during the study will be the dependent variable. Study subjects will be considered as random effects, treatment group and visit number as fixed effects.

Patient compliance was monitored via patient questionnaires on the date of surgery. If compliance rate differed significantly, it would be labeled as a confounding factor.