Steri3X ~ Clinical Studies

Clinical Study: Cesarean Section

Steri3X has been utilized in clinical settings, such as a Phase 2 clinical trial conducted by the University of Tennessee, to assess its effectiveness in preventing surgical site infections following cesarean sections.

Steri3X for Cesarean Section Wound Infection Prevention

Recruiting Site:	Memphis, Tennessee
Overseen By:	Bethany Erickson, MD
Age:	Any Age
Sex:	Female
Trial Phase:	Phase 2
Lead Sponsor:	University of Tennessee
No Placebo Group:	All trial participants will receive the active study treatment (no placebo)
Prior Safety Data:	This treatment has passed at least one previous human trial

Trial Summary

Trial purpose:

Postpartum infection if a major cause of maternal morbidity and mortality and surgical site infections are some of the common complications following cesarean section. This study aims to determine the effect of Steri3X on the incidence of cesarean section SSI at Regional One Hospital.

Eligibility Criteria

This trial is for women aged 16 or older undergoing cesarean sections, including first-time and repeat procedures. It's suitable for those with diabetes or obesity. Women must not have current infections like chorioamnionitis, be using other wound treatments like Prevena, have had membranes ruptured over 24 hours, or be on antibiotics (except for GBS prophylaxis).

Inclusion Criteria

Age 16 years old or older

C-section patients only (primary, repeat, or stat)

Patients receiving PCN for GBS prophylaxis ok to include (but not required)

Exclusion Criteria

Rupture of membranes >24 hours

You are currently using a device called Prevena or any other wound vac.

Chorioamnionitis or other existing infection excluded (Single maternal fever >39 C, 2 maternal fevers > 38, or clinical risk factors for chorioamnionitis)

Treatment Details

Interventions

Steri3X (Antimicrobial Coating)

Trial Overview

- The study tests Steri3X's effectiveness in preventing surgical site infections after cesarean sections compared to a control group without it. Participants will receive the Steri3X treatment immediately after their operation at Regional One Hospital.
- Two Participant Treatment Groups

Group I:

Experimental Treatment Intervention

Patients randomized to the Experimental group will receive treatment with Steri3x immediately following closure of the Cesarean section incision. Participants in the experimental group will receive approximately 48 hours of post-op hospitalization and wound surveillance.

Group II:

Active Control Intervention

Currently, the standard of care for Cesarean section patients includes covering the closed incision with a sterile bandage to reduce the chance of infection, and approximately 48 hours of post-op hospitalization and wound surveillance. The "control" group will receive post-operative wound dressings consistent with the current standard of care.

Steri3X ~ Clinical Studies

Clinical Study: Shoulder

Presurgical application of Steri3X in shoulder arthroplasty to prevent bacterial contamination and post-surgical infection

Principal investigator (Baptist Health Lexington): Dr. Daniel Hackett, MD

Sub-investigator (Baptist Health Lexington): Dr. Kaveh Sajadi, MD

Brief Protocol Summary

The study is designed as a single-blinded, prospective multicenter trial with the aim of comparing the rate of culture positivity in patients undergoing primary shoulder arthroplasty. It will enroll 80 patients across participating sites. The patients will be randomized into two groups: a control group of 40 patients who will receive standard peri-operative antibiotics and skin preparation, and a Steri3x cohort of 40 patients who will receive the same standard care plus an application of Steri3x on the epidermal layer before incision and another application on the dermal layer immediately after incision

Cutibacterium acnes (C. acnes) is a relatively slow growing, aerotolerant anaerobic gram-positive bacillus bacteria that lives primarily in the sebaceous glands of humans. While commonly found within normal skin flora, C. acnes can, on occasion, contaminate wounds during primary shoulder arthroplasty and result in post-operative infections. Interestingly, standard peri-operative antimicrobial preparation along with peri-operative antibiotics have not been shown to be highly effective in reducing the bacterial load of C. acnes. This relative ineffectiveness is due to its location deep to the epidermal layer. Due to the relative lack of utility with common topical skin preparation, other studies have investigated the efficacy of agents that would reduce the bacterial load of C. acnes; however, these skin preparations such as topical benzoyl peroxide (BPO) have only been shown to be effective pre-operatively. Despite BPO's effect on bacterial load, there are multiple studies demonstrating positive C. acnes cultures even after 3 to 5 days of pre-operative preparation of the surgical site. And despite this effectiveness, the overall infection rate after primary shoulder arthroplasty remains relatively high (0.9-2.9%).

Steri3x is an FDA approved, microbicidal liquid polymer that forms an occlusive elastomeric barrier. It is reported to be effective against MRSA, MSSA, and C. acnes, among many other organisms. The novelty of this application will be its use in creating both an antimicrobial environment and physical barrier on the epidermal and dermal layer of the surgical site, preventing contamination of the wound with microbes within the dermal and epidermal layers.

While the use of liquid polymers has been shown to prevent infections in other surgical specialties, there is limited data available for its use in shoulder arthroplasty. Therefore, we propose a single-blinded, prospective multicenter trial with the aim of comparing the rate of culture positivity in patients undergoing primary shoulder arthroplasty. Patients will be separated into two cohorts. Both will undergo standard surgical preparation; however, only 1 cohort will receive Steri3x

application. For both cohorts, culture swabs will be utilized to culture the epidermal layer prior to incision, the dermal layer after incision, the glenoid rim after implant placement, and the dermal layer upon deep layer closure. Cultures will be held for 14 days. Our primary outcome measure will be to evaluate culture positivity. Our secondary outcome measures will include assessing wound healing and signs/symptoms of post-operative infection during the first three post operative visits. Our hypothesis is that the use of Steri3x will reduce culture positivity rates at the time of primary shoulder arthroplasty, while having no adverse effect on wound healing and post-operative infection.

If lower culture positivity is found with the use of Steri3x, this could significantly change the way we approach standard skin and antibiotic preparation for shoulder arthroplasty/open shoulder surgeries. Given the morbidity and economic impact associated with periprosthetic infection, by lowering contamination of the wound, we could dramatically lower infection rates. This could have a profound effect on lowering infection rates with use of this product.

Study Design

This study is a multi-site, single blinded randomized trial. A total of up to 80 subjects will be randomized in a 1:1 allocation to the Experimental Arm or the Control Arm with a maximum enrollment of 40 Steri3x and 40 control subjects. Subjects in Both Arms will receive standard preparation of procedure and peri-operative anti-biotics. Subjects will be followed up from when they sign the ICF to their 90-day follow-up visit after surgery. Follow-up visits scheduled at regular time intervals following standard of care including those at 2-weeks, 6 weeks, and 90 days post-operatively.