

## Poster abstract submission

**Approval Status**

Not Started

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**Poster title**

The Impact of XF-73 Nasal Gel on the Nasal Decolonisation of *S. aureus* and the Use of Post-Operative Anti-staphylococcal Antibiotics in Cardio-vascular Surgery Patients in a Phase 2b Study

**Poster abstract**

*Staphylococcus aureus* carriers have a higher risk of staphylococcal infections after invasive medical/surgical procedures. Reducing *S. aureus* nasal carriage is one method for reducing the risk of surgical site infections (SSIs) in orthopaedic, cardiac and general surgery. Exeporfinium chloride (XF-73) is a topical, fast-acting drug with a low propensity for engendering bacterial resistance which is being developed for nasal decolonization of *S. aureus* to prevent surgical site infections. Cardiac surgery patients were enrolled in a randomized, placebo-controlled Phase 2b trial to investigate XF-73 nasal *S. aureus* decolonization. *S. aureus* positive patients were randomized (1:1) to XF-73 nasal gel vs. placebo, administered 5x over ~24 hrs prior and immediately after surgery. Within 24 hours after starting treatment (1 hour pre-surgery), patients who received XF-73 in the micro-ITT population showed an adjusted mean reduction of 2.5 log<sub>10</sub> in their nasal burden of *S. aureus* compared with a 0.4 log<sub>10</sub> reduction for placebo (Figure 1). One hour post-surgery, 74.4% of patients treated with XF-73 showed eradication of *S. aureus* nasal carriage versus 25% with placebo. No SSIs were identified in either group and a  $\geq 2.7$  log<sub>10</sub> CFU/mL decrease in *S. aureus* nasal carriage was maintained up to 6 days post-surgery in the XF-73 arm. For post-operative ( $\geq 48$  hrs) antibiotic administration, 57.8% of all trial patients received anti-staphylococcal antibiotics and the mean durations were similar in both treatment groups; however, statistically significantly fewer patients in the XF-73 treatment arm compared to placebo received post-operative anti-staphylococcal antibiotics (20/43, 46.5% vs. 28/40, 70% respectively  $p=0.045$ ), which suggests that antibiotics may have been prescribed as an early intervention in more patients in the placebo arm. The observed reduction of use of post-operative antibiotics in the XF-73 arm is consistent with the principles of good antimicrobial stewardship which are crucial for managing and preventing infections more effectively and for maintaining the long term efficacy of antibiotics, reducing healthcare complications and improving patient safety. Phase 3 studies are being planned to evaluate and gain regulatory approval for XF-73.

Research topic

Clinical development

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