Multicenter, randomized controlled, observer-blinded study of a nitric oxide generating treatment in foot ulcers of patients with diabetes—ProNOx1 study

Edmonds ME et al. Wound Repair Regen 2018; 26: 228-237

Randomized Controlled Trial (RCT) Aims

Assess the safety and efficacy of EDX110 (ConvaNiox™), a nitric oxide-generating dressing indicated for the treatment of diabetic foot ulcers (DFUs) compared to standard of care (SoC) dressings.

RCT Design

Recruitment from **10** multidisciplinary diabetic foot ulcer clinics.

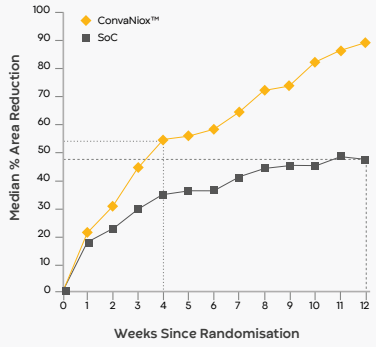
Total of **148** ulcers among 135 patients.

Treatment period of **12** weeks or until fully healed + 12 week follow-up period.

Percentage Area Reduction

ConvaNiox™ resulted in **3x** faster DFU area reduction compared to SoC dressings. Percentage area reduction (PAR) at week 4 for ConvaNiox™ arm was equivalent to PAR at week 12 in SoC arm (ITT, PP)*.

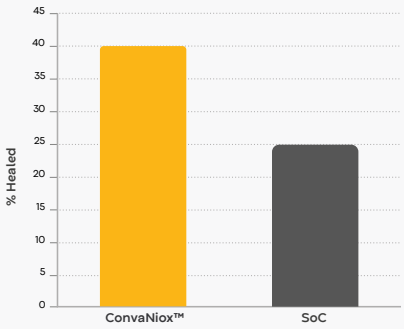
Median PAR at 12 weeks for ConvaNiox™ vs. SoC dressings.TT: 88.6% vs 46.9% (p=0.016), below:



Complete Healing

ConvaNiox™ resulted in **60%** more DFUs healed compared to SoC dressings. ConvaNiox™ resulted in significantly more completely healed DFUs at week 12 compared to SoC dressings in both ITT and PP analysis.

ITT: 40% vs. 25% (p=0.049), below:



Safety Analysis

No significant difference in adverse event (AE) occurrence between the study groups:

49 ConvaNiox™ **in 32 patients**

vs.

54 SoC dressings **in 34 patients**

The difference in the occurrences of serious adverse effects (SAEs), related or possibly related to the ulcer, was statistically significant (p=0.049) in favour of ConvaNiox™.

4 SAEs in ConvaNiox™ arm **vs.** **11** SAEs in SoC arm

*ITT: Intention to treat, PP: Per protocol

Further Information

Infected ulcers were included in the RCT with 30% of ulcers in ConvaNiox™ arm and 34% in SoC being clinically infected at baseline. Infected ulcer treatments included use of antibiotics.

32% of SoC dressings were classed as antimicrobial (iodine, honey, polyhexanide, bacterial binding).

Key Takeaway

This study demonstrated the ability of ConvaNiox™ to achieve significantly faster wound area reduction, and support complete healing of significantly more DFUs after 12 weeks, compared to SoC dressings within a generalizable and clinically relevant population.

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