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ABSTRACT

Evaluation of intact fish skin grafts plus standard care in the treatment of venous leg ulcers: an interim analysis of the THOR trial

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Abstract

Background: Venous leg ulcers (VLUs) are nonhealing wounds that pose considerable clinical and economic challenges. Healing outcomes with existing standard-of-care (SOC) remain limited, creating a pressing need for more effective therapeutic options

Methods: An interim analysis of this randomized controlled multicenter clinical trial evaluated intact fish skin graft (IFSG) and SOC versus SOC alone in nonhealing VLUs. The primary end-point was the percentage of target ulcers achieving complete wound closure in 12 weeks, defined as 100% re-epithelialization without drainage for two consecutive weeks, confirmed by blinded independent review.

Results: The statistical analysis revealed that the treatment arm trended toward improved full wound closure at 12 weeks over SOC by 1.52 (credible interval: 1.37–2.22) in terms of relative risk (Treatment/SOC). This translates to an improvement of 8.53% (credible interval: 5.60%-19.7%) in percentage terms. In the ITT population, the IFSG + SOC arm achieved a 47.6% closure rate versus 21.7% with SOC alone, a 25.9% absolute gain that was not statistically significant (n = 21, 95% CI -0.02% to 0.493%, p = 0.07, α = 0.05). In the ITT and PP population, IFSG + SOC achieved a higher mean area reduction than SOC.

Conclusion: The interim analysis demonstrated a positive trend favoring IFSG products over SOC alone. While the present interim analysis provides promising early results, limitations inherent to its preliminary nature warrant consideration. The alignment of these interim findings with the broader body of evidence reinforces biological plausibility and strengthens confidence that the final analysis will yield clinically meaningful results supported by high-quality evidence.

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