LEVEL I EVIDENCE | LHACM PUBLISHED STUDY

Evaluation of Lyophilized Human Amnion/Chorion Membrane (LHACM) in the management of nonhealing Diabetic Foot Ulcers (DFU)

An interim analysis of the CAMPAIGN Prospective Randomized Controlled Trial (RCT)

BACKGROUND: Chronic DFUs remain a significant challenge and are associated with high rates of infection, hospitalization, and amputation. The CAMPAIGN RCT was designed to assess whether LHACM, when added to a standardized Standard of Care (SOC) regimen, improves clinical outcomes.

- N=88 randomized patients
- 12 Weeks
- 47% Closure Rates with LHACM plus SOC @ 12 Weeks
- 21% Closure Rates with SOC alone @ 12 Weeks

STUDY DESIGN & METHODOLOGY

Design: Prospective, multicenter, RCT

4-Week Run-In Period: Subjects received standardized SOC during screening. Ulcers with ≥20% area reduction during run-in were excluded to ensure enrollment of non-healing DFUs

Interim Analysis: N=88, randomized patients

Planned Enrollment: N=150, randomized patients

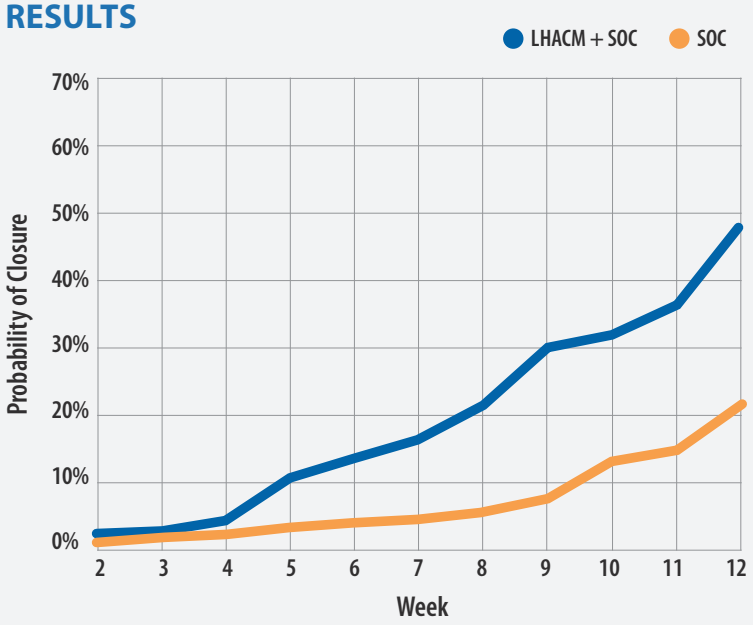
Comparison Arms: LHACM + Standard of Care (SOC) compared to SOC alone. SOC Included:

- Sharp/mechanical debridement
- Moisture-appropriate dressing (calcium alginate or foam)
- Infection evaluation and management
- Mandatory offloading, including use of the Foot Defender® where appropriate

Primary Endpoint: Probability of complete closure at 12 weeks.

Methodological Approach: The CAMPAIGN trial used a Bayesian Framework which is explicitly supported by CMS.

RESULTS



At 12 weeks:

- 47% of wounds achieved complete closure with LHACM plus SOC
- 21% of wounds achieved complete closure with SOC

Bayesian Framework: LHACM exceeded the interim superiority threshold of >90% with a posterior probability of 98.5%, supporting a high confidence of its clinical benefit.

CONCLUSION: The CAMPAIGN interim RCT demonstrated that LHACM provided a clinically meaningful advantage over SOC alone, nearly doubling closure probability by 12 weeks. These results reinforce the role of evidence-based amnion/chorion allografts in DFU management for high-quality clinical evidence.

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Call: 866.477.4219 or email: customerservice@mimedx.com

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