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Introduction

Venous leg ulcers pose significant clinical, humanistic and economic burdens on society. Standard of care (SOC), multi-layer compression, results in healing of only 50% of venous leg ulcers in 12 weeks. Dehydrated Human amnion/chorion membrane* (dHACM) promotes healing by replacing damaged extracellular matrix and providing cytokine growth factors.

This randomized controlled clinical trial was designed to evaluate the efficacy of dHACM in the treatment of venous leg ulcers. A surrogate endpoint of percentage reduction in surface area at 4 weeks was employed.

Methods

A multi-center, randomized, controlled open-label clinical trial evaluating the safety and efficacy of dHAM (1 application or 2 applications two weeks apart) plus multi-layer compression versus multi-layer compression alone (Coban-2, 3M) in the treatment of venous leg ulcers was conducted at six geographically distinct sites in the United States.

The trial utilized a surrogate endpoint which is known to be a predictor of healing at 12 weeks: The primary outcome measure was the proportion of ulcers achieving 40% wound closure at 4 weeks comparing MCT alone to one or two applications of dHACM.

Acknowledgements

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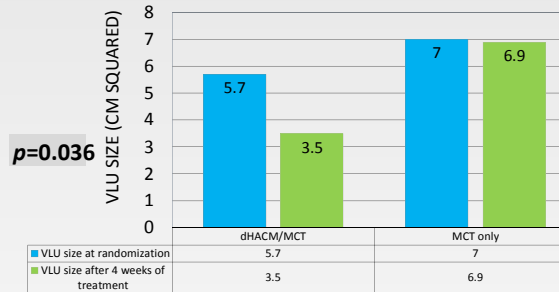
Case example. #1: 1 dHACM application.
Wound reduced 84% at 4 weeks -5.5 cm² to 0.9 cm²



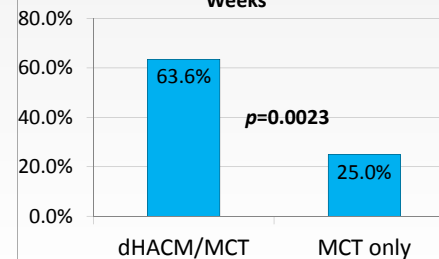
Case example. #2: 2 dHACM applications.
Wound reduced 90.5% at 4 weeks -2.1cm² to 0.2 cm²



VLU Size at Randomization vs. Week 4



>/=40% Reduction in VLU Size at 4 Weeks



Results

90 participants have been enrolled to date in this ongoing trial. 68 have completed the study: 44 ulcers were randomized to receive dHACM (1 or 2 applications) and 24 received MCT alone.

Outcomes were similar within the dHACM group. Comparisons between combined dHACM groups versus MCT group presented in figures.

Conclusions

Dehydrated human amniotic membrane resulted in more rapid healing of venous leg ulcers compared to standard of care at the surrogate endpoint of percentage of wound area reduction at four weeks.

*EpiFix® - MiMedx Group Inc., Marietta, GA
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References

- Zehlen C, Serena TE, Denozieri G, Fetterolf DE. A prospective randomized comparative parallel study of amniotic membrane wound graft on the management of diabetic foot ulcers. *Int Wound J* 2013. DOI 10.1111/iwj.12097.

