A Prospective, Randomized, Controlled, Multi-center, Clinical Trial Examining Healing Rates, Safety, and Cost to Closure of An Acellular Reticular Allogenic Human Dermis® Versus Standard of Care in the Treatment of Chronic Diabetic Foot Ulcers

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Acyclic Reticular Dermis® has been shown to have high cytokine and have high clinical and shown to significantly increase diabetic foot wounds for up to 20 years. This study comprised a multi-center trial to examine clinical efficacy and safety of a cell-free allogenic reticular dermis (AD) for healing chronic diabetic foot ulcers. A total of 12 weeks, patients with type 2 diabetes mellitus and chronic foot ulcers were randomized to receive either standard of care with or without AD. Diabetic foot ulcers were localized and classified as either major or minor wounds. The primary outcome was the percentage of wounds that were healed at 12 weeks. Secondary outcomes included the percentage of wounds that were healed at 12 weeks, the percentage of wounds that were healed at 24 weeks, the percentage of wounds that were healed at 12 weeks, and the percentage of wounds that were healed at 24 weeks. The study was concluded in the third quarter of 2014 and published in "Clinical Practice of Advanced Wound Care" (NCT02331147).

METHODS

Background

Study participants were randomized to receive either standard of care with or without AD. Diabetic foot ulcers were localized and classified as either major or minor wounds. The primary outcome was the percentage of wounds that were healed at 12 weeks. Secondary outcomes included the percentage of wounds that were healed at 12 weeks, the percentage of wounds that were healed at 24 weeks, the percentage of wounds that were healed at 12 weeks, and the percentage of wounds that were healed at 24 weeks. The study was concluded in the third quarter of 2014 and published in "Clinical Practice of Advanced Wound Care" (NCT02331147).

RESULTS

CONCLUSIONS

This study demonstrated that the ADs treated with ADs were associated with improved healing rates compared to standard of care at 8 and 12 weeks. Level 1 evidence supports the use of ADs for healing chronic DFUs. Wound size and specific types may play a role in the efficacy of ADs in the treatment of chronic DFUs.