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ABSTRACT

A prospective, multicenter, randomized, controlled trial of non-healingdiabetic foot ulcers treated with standard care with or without br-ac: top-line results

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Abstract

Aims: The primary objective of this randomized controlled trial was to determine whether non-ischemic, non-infected Wagner Grade 1-2 diabetic foot ulcers (DFUs) treated with standard care plus BioRetain Amniochorion (BR-AC) resulted in a higher probability of complete wound closure compared to standard care alone.

Methods: Following a two-week run-in and stratified randomization, subjects attended clinic weekly for 12 weeks or until complete healing was observed. At each visit the wound was measured, debrided as needed, evaluated for infection and treated with or without BR-AC, followed by application of a non-adherent wound contact layer, a foam pad, alginate or hydrofiber dressing for moderately draining wounds, and a secondary retention bandage, including a standardized off-loading device. Bayesian statistics were used to evaluate the likelihood of healing.

Results: The Intent to Treat (ITT) analysis showed a posterior mean absolute difference in healing rates between treatment and control of 0.22 (95% CrI: –0.01 to 0.45), with a 96.8% posterior probability that the effect exceeds zero and a posterior mean risk ratio of 1.9 (95% CrI: 0.87–3.2). The posterior mean probability of closure was 0.31 (95% CrI: 0.15–0.47) for the standard of care (SOC) arm (3% higher than the prior probability) compared with 0.53 (95% CrI: 0.34–0.74) for the treatment arm (18% higher than the prior probability). The treatment distribution was centered substantially higher, with limited overlap between intervals. The SOC arm showed a 36.4% posterior probability of closing by more than 50% at 12 weeks, compared with a 56.4% posterior probability for the treatment arm.

Conclusion: This is the first controlled DFU trial examining a birth tissue product prepared using the 'Bioretain' method designed to retain integrity and contents. With only a 3.2% probability that BR-AC is not superior to SOC, these results provide strong evidence of treatment benefit.

Conflicts of interest: Mr. McCoy, Mr. Tunyiswa and Dr. Slade provided services to BioStem under contract and hold no financial interest in the company. Dr. Weston is employed by BioStem Technologies, Inc., which funded this trial.
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