Clinical Trial Protocol ENC-HEL-DFU-02 Data Analysis: 24 Patients

A Randomized Controlled Clinical Trial Evaluating The Efficacy Of A Unique Advanced Bioengineered Skin Substitute with Standard of Care Versus An Active Comparator with Standard of Care In The Treatment Of Non-Healing Diabetic Foot Ulcers

26th December 2024

To Whom it May Concern,

I am providing this letter of support in regards to the above clinical trial where I analyzed a randomized prospective trial designed to evaluate the use of an advanced high-purity type-I collagen-based skin substitute (Helicoll®) that is 510K approved for application in the management of multiple wound types including the diabetic foot ulcer (DFU). Helicoll® is a translucent, off-white, semi- occlusive, self-adhering and pre- sterilized Type-I Collagen Sheet for use as a bioactive membrane. It is a reconstituted collagen sheet free of contaminants like lipids, elastin, and other immunogenic proteins, and is flexible with moderate tackiness. The purpose of this clinical evaluation was to compare patient outcome data on Helicoll® versus other commercially available human amnion based products.

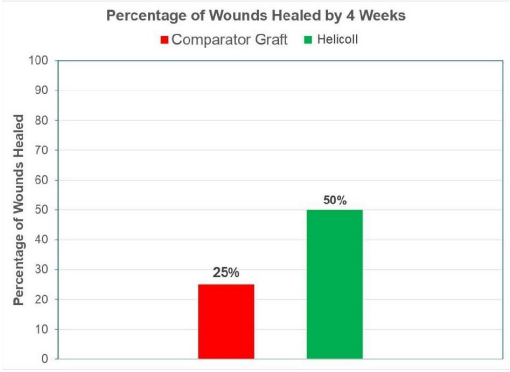
Study variables were summarized as means and standard deviations (±SDs) for continuous variables as well as medians for non-normal data. Categorical variables were presented as counts and proportions or percentages. Statistical testing between treatment groups at baseline was carried out to examine the success of randomization. For categorical variables, chi square or Fisher exact tests were performed and for continuous variables independent t tests or Mann- Whitney tests were used (depending on variable normality) to test for statistical differences. The PAR for the index wound at X weeks was calculated as $((A_I - A_{XW})/ A_I)*100$, where A_I is the area of the index wound at randomization and A_{XW} the area at X weeks.

Out of 27 subjects who were screened at 3 sites, 24 subjects were randomized: 12 to HeliColl, and 12 to a comparator graft (Epifix or Grafix). A comparison by treatment group for key wound-related variables showed that variables were well balanced between groups

Summary Statistic for the primary endpoint , Mean PAR values, weeks 1-4 post randomization by treatment group are shown below :

Treatment Group	Week 4
Comparator graft	71.3
Helicoll	83.9

For the main secondary endpoint, complete wound healing by 4 weeks , the comparator graft healed 3/12 while the Helicoll healed 6/12.



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This data is very similar to a prior study published comparing amnion graft to Helicoll. Therefore, in my opinion as an expert in analyzing wound care trials these results are very promising and I would highly recommend CMS reconsider Helicoll for approval. Feel free to contact me with any questions.

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