A Non-Randomized Open Label Clinical Trial Evaluating DermaBind TL

NCT07172893

Status	RECRUITING
Phase	Phase 4
Sponsor	HealthTech Wound Care
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (17)

- \. Be an adult between 18 and 80 years of age at the time of consent 2. Presence of a DFU, Wagner Grade 1 or 2 (see Appendix A for definitions) on the plantar, lateral or dorsal aspect of the foot, extending through the dermis provided it is below the medial aspect of the malleolus.
- \. Subjects must have a diagnosis of Type I or Type II diabetes mellitus (DM) as defined by the American Diabetes Association
- for Type I DM, have been on a stable anti-diabetic treatment for at least 30 days before the baseline visit, or
- for Type II DM, must have been on a stable anti-diabetic medication for at least 30 days, or if diet-controlled only, must have been on stable diet-control for at least 6 months.
- \. For Type I and Type II DM, A1C must be equal or \<10% in the last 30 days, or confirmed during the screening period (SV1 up to TV1) 5. Have a single target ulcer 6. If other DFU wounds are present on the same foot, they must be more than 2 cm distant from the index ulcer. \[NOTE: If two or more DFUs are present with the same grade on the same foot, the index ulcer is the largest ulcer and the only one evaluated in the study.\] 7. Have a wound with an area greater than 1cm2 and less than 25 cm2 and does not probe to bone 8. Index ulcer has been present for greater than 4 weeks prior to SV1 and less than 1 year, as of the date the subject consents for study.

... and 12 more (see full listing online)

Exclusion (6)

- \. Pregnant or lactating 2. Less than 18 years of age 3. Has continued tobacco use 4. Have a wound that decreased in size e30% between the Screening and Treatment Visits 5. Wound is showing signs of healing and that improvement is likely to continue without treatment (increased granulation, epithelization, decrease in size e 30% reduction in wound surface area).
- \. Circulating hemoglobin A1c exceeding 10% within 30 days of the Screening Visit 7. Serum creatinine concentrations of 3.0 mg/dL or greater within 30 days prior to screening 8. The wound has been treated with biomedical or topical growth factors within the previous 30 days before the screening visit 9. Need for any additional concomitant dressing material other than the ones approved for this study 10. Osteomyelitis or bone infection of the affected foot as verified by x-ray or other radiographic modality within 30 days prior to the first screening visit. (In the event of an ambiguous diagnosis, the Principal Investigator will make the final decision).
- \. The inability to tolerate off-loading (a surgical shoe, removable cast walker or a total contact cast) 12. Have a known or suspected disease of the immune system 13. Have an active or untreated malignancy or active, uncontrolled connective tissue disease 14. Subjects with a history of more than two weeks of treatment with immune-suppressants (including systemic corticosteroids \>10mg daily dose), cytotoxic chemotherapy, or application of topical steroids to the ulcer surface within 1-month prior to first SV1, or who receive such medications during the screening period or who are anticipated to require such medications during the course of the study.
- \. At the index ulcer site, presence of necrosis, purulence, or sinus tracts that cannot be removed by debridement 16. Had undergone a revascularization procedure aimed at increasing blood flow in the treatment target limb less than 4 weeks before the baseline visit 17. Have serum aspartate aminotransferase, alanine aminotransferase, or alkaline phosphatase levels greater than three times the normal upper limit within 30 days prior to screening 18. Uncontrolled edema, lymphedema or venous HTN in the limb of the index ulcer 19. Undergone treatment to the index ulcer with a living skin equivalent within the last 4 weeks before screening 20. Undergone treatment to the index ulcer with a placental-derived allograft within the last 4 weeks before screening 21. Has the presence of any condition that in the opinion of the investigator places the subject at undue risk or potentially jeopardizes the quality of the data to be generated 22. Subjects on any investigational drug(s) or therapeutic device(s) within 30 days preceding SV1.
- Index ulcer(s) deemed by the investigator to be caused by a medical condition other than diabetes.

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... and 1 more (see full listing online)

Locations (10 total)

Midland Florida Clinical Research Center, DeLand, Florida, United States
Pharmakon Medical Research, Palm Beach Gardens, Florida, United States
Vital Medical Research, Sweetwater, Florida, United States
... and 7 more locations

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