Kushnir Igal et al., J Regen Med 2017, 6:4
DOI: 10.4172/2325-9620-C1-005

A PROSPECTIVE, OPEN-LABEL, UNCONTROLLED STUDY EVALUATED THE CLINICAL PERFORMANCE OF RD1 IN CHRONIC DIABETIC FOOT ULCERS AT THREE WOUND CARE CLINICS IN THE USA

Kushnir Igal[a], **Snyder Robert J**[a], **Maria Kasper**[a] and **Serena Thomas E**[b]
[a]RedDress Ltd, Israel
[b]Serena Groups, USA

Statement of the Problem: Chronic wounds stall in the inflammatory phase of wound healing characterized by the presence of non-viable tissue, excessive bacterial burden, and the presence of increased inflammatory cytokines. The RedDress Wound Care System (RD1; RedDress Ltd, Israel), is an autologous, biodegradable fibrin scaffold that recreates the functional wound healing environment with minimal risk of immunorejection. The primary objective of this study was to determine safety and efficacy of the RD1 in the treatment of diabetic foot ulcers (DFU).

Methodology & Theoretical Orientation: Following a screening period of 2 weeks, wounds were treated weekly for up to 12 weeks with the RD1. 20 subjects with 20 DFUs were enrolled at 3 sites in the USA. Two subjects were not compliant with the protocol, resulting in 20 subjects for the ITT (intent-to-treat) analysis and 18 for the PP (per protocol) analysis.

Findings: Safety: The mean AE rate for both ITT and PP populations was 1.6. Efficacy: The proportion of wounds completely healed in the ITT and PP populations was 13/20 (65%) and 13/18 (72%), respectively. There were 4 occurrences of ulcer recurrence following initial healing, with 2 occurrences resulting in unhealed wounds (same for ITT and PP). Percentage area reduction (PAR) for the ITT population at 4 and 12 weeks was 61.3% and 66.6%, respectively; the figures for the PP population were comparable at 4 weeks but better at 12 weeks: 60.0%, and 76.1%, respectively. Mean time to heal in the ITT population was 59 days and 56 days in the PP population.

Conclusion & Significance: The study demonstrated the safety and efficacy of the RD1 in treating DFUs and the use of a natural autologous blood clot as a mean to support healing in DFUs.

Biography

Igal Kushnir, Founder, RedDress Ltd: Holder of other medical device patents; invented a device in body thermoregulation for MTRE Advanced Technologies of which he was the founder and CEO for 5 years; invented a non-invasive functional imaging device of body organs such as the lungs and heart for Deep Breeze Ltd. of which he was the founder and CEO for 7 years; Lead the closure of a strategic contract with GE Healthcare and brought the company to full commercialization; vast experience as a family physician specializing in Pediatrics; has had a private clinical practice for the past 30 years; for 10 years held the position of chief physician and medical manager for a hospital for chronically ill patients; graduated cum laude from Tel Aviv University (Israel) and holds a Medical Degree specializing in Pediatrics.

dr@igalkushnir.com

Notes: