Recombinant human epidermal growth factor (REGEN-D 150): effect on healing of diabetic foot ulcers.

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Abstract

Recombinant human epidermal growth factor (REGEN-D 150), which was cloned and over expressed in E. coli, has shown enhanced healing of chronic diabetic foot ulcers (DFU) by significantly reducing the duration of healing in addition to providing excellent quality of wound healing and reepithelization. Post-marketing surveillance (PMS) study of REGEN-D 150 in 135 patients of DFU in India was compared with Phase III clinical trial data of REGEN-D 150 in India. Statistical analysis of study data determined that the empirical survival probability distribution, in terms of non-healing of ulcers, was lowest in the case of PMS study, better than that for Phase III; more DFU patients were healed in PMS study. Percentage of patients cured in any given week (e.g., in week 10) is above 90% in PMS study, as compared to 69% in Phase III clinical trial; this percentage was around 18% for the control group with placebo in the Phase III trial. The average wound healing time was significantly lower in PMS study, 4.8 weeks, while it was 9 weeks in Phase III clinical trials while the average wound healing with REGEN-D 150 was found to be 86% in this study. REGEN-D 150 has been found to result in healthy granulation and stimulate epithelization, thus leading to final wound closure. The PMS study has established the efficacy of REGEN-D 150 in faster healing of diabetic foot ulcers.

PMID: 17655964