

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.

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