

**Project No. : 3493/2006**

**Randomized Controlled Trial to assess the efficacy of Topical Recombinant Human Platelet Derived Growth Factor in patients with Chronic Diabetic Lower Limb Ulcers**

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**OBJECTIVES**

Lower extremity ulcers are a serious complication of Diabetes Mellitus (DM) and account for more than 60% of all non-traumatic lower leg amputations. These ulcers exhibit decreases in angiogenic response and the production of growth factor. This study was conducted to evaluate the efficacy of rhPDGF in diabetic foot ulcers.

**METHODOLOGY**

This prospective randomized controlled trial was conducted from May 2006 to May 2008. Fifty patients with type I or type II DM and chronic ulcers of at least four weeks duration were studied. They were randomized in to two groups, each consisting of twenty five patients, on the basis of computer generated numbers. The patients in group "A" (Test Group) received treatment with topical application of rhPDGF gel and those in Group "B" (Control Group) were treated with local application of a placebo (KY Jelly). In addition, a standardized regimen of good wound care was provided to both groups. A 75% reduction in size of the wound, or a period of ten weeks after commencement of treatment, whichever occurred earlier, was taken as the end point.

**RESULTS**

The mean age of the patients was 49.9+18.8 years in the control group and 56.2+ 11.2 years in the test group. The median duration of ulcer at time of enrolment in the study was 6 weeks in control and 5 weeks in test group. The mean BMI was 21.8+3.2 in control group and 22.9+3.3 in test group. 15 ulcers belonged to IAET (international Association of Enterostomal Therapy) class III and 10 ulcers belonged to IAET class IV in control group where as 16 ulcers were in IAET class III and 9 ulcers in IAET class IV in test group. The mean size of the wounds was 26.5+2.5 cm<sup>2</sup> in control group and 29.9 ±3.4 cm<sup>2</sup> in test group. All patients tolerated the test medication well. At the end of 10 weeks, 18 ulcers had healed in control group and 15 in test group.

**RECOMMENDATIONS**

This study has not shown any statistically significant improvement in ulcer healing rates after the use of topically applied rhPDGF and its use can be recommended only as a supplement to the standard methods of ulcer care. The high cost of the medication, stringent storage requirements and prerequisites like the presence of an adequate blood supply, and good infection and glycemic control prior to its application preclude its widespread use by patients.