

Investigation the safety of Amniotic membrane extracts to improve diabetic foot Ulcers (Phase 1 Clinicaltrial Study)

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Abstract

Background: For nearly 100 years, amniotic membranes have been used to treat various types of skin wounds. Amniotic extract is one of the derivatives of amniotic membrane that contains all the properties of amniotic membrane. The aim of this study was to evaluate the safety of the amniotic membrane extract in the treatment of diabetic ulcers.

Methods: This study was an Open labeled clinical trial without control group. A total of 10 patients with Wagner Grade 2 diabetic foot ulcers were selected in both sexes. The extract was used every 48 hours in the first week and every 72 hours from the second week until the end of the wound treatment. Patients were followed up weekly until wound healing.

Results: In this study 80% of patients were men and 20% were women with mean age (56.7 ± 8.7) years. The ulcer duration was 8.9 ± 2.12 weeks. The mean area of ulcers at the time of entry into the wound group ≥ 500 mm², 977.5 ± 201.9 and in the wound group ≤ 500 mm² was 145.6 ± 36.4 . At 4 weeks post treatment, the wound healing rate in the wound group was ≤ 500 mm², 98.9 ± 2.40 % and in the wound group ≥ 500 mm² was 92.1 ± 7.23 %. in sixth week of treatment, ulcers were complete closure in both groups.

Conclusion: The results of this study suggest that the use of amniotic extract can be effective in the healing of diabetes foot ulcer without any side effects.

Biography

Mohammad azimi Alamouti, 31 years, PhD candidate in tissue engineering in royan institution, Iran. I'm director of wound clinic in royan institution, Iran. I'm research in skin substitute and wound management. I have 4 publication and 2 article under review.

Publications

1. Remyelination of the Corpus Callosum by Olfactory Ensheathing Cell in an Experimental Model of Multiple Sclerosis, December 2014 Acta medica Iranica 53(9)
2. Extract, culture and seeding of CD93 hematopoietic stem cells on PCL-gelatin Nanofiber scaffold for tissue engineering



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