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RANDOMIZED PHASE III STUDY COMPARISON BETWEEN RADIODERM SPRAY VERSUS PLACEBO AS A PROPHYLACTIC AGENT ON RADIO-INDUCED CUTANEOUS TOXICITY IN WOMEN UNDERGOING RADIOTHERAPY ON THE BREAST

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Purpose: The objective of the study is the evaluation of the effectiveness of Radioderm Spray (hyaluronic acid with amino acids constituents of collagen), compared with placebo (consisting of gel alone), in preventing or reducing the appearance of radio-induced skin erythema in women subjected to breast irradiation.
Materials and Methods: 100 patients were randomized in 2 groups: Radioderm Spray (53 patients) vs. placebo (47 patients) without any preference at the time of randomization. Radiation therapy was given in 30 fractions (2 Gy daily): 50 Gy on the breast volume and sequential boost of 10 Gy on the tumor bed up at a total dose of 60 Gy. Patients applied the product three times a day, starting from the first day of treatment up to two weeks after the end of the radiotherapy cycle. The cutaneous toxicity was evaluated. Patients were also given a questionnaire on quality of life and on the cosmetic outcome.
Results: Using the RTOG toxicity scale there was no statistically significant difference as regards the maximum cutaneous toxicity during radiotherapy between Radioderm Spray (7%) and placebo (7.5%) ($p = 0.09$). Furthermore, there was no statistically significant correlation between the maximum toxicity and the patient's habitus (breast size). Although there is no statistical significance we can observe a trend between the patient's habitus and skin toxicity: patients with large breasts show a higher toxicity ($p = 0.06$). Patients with large breasts who received the Radioderm Spray had less toxicity within six weeks of radiotherapy. It was finally observed a delay in the appearance of cutaneous erythema G1 (on average of 6 radiotherapy sessions) in patients treated with Radioderm Spray

Conclusions: Although there is no overall difference between placebo and Radioderm Spray in prevention (occurring at the 18th session on average) compared to those treated with placebo (12th session on average), a statistically significant result ($p < 0.05$).
or in the duration of the radio-induced erythema, a delay in the appearance of G1cutaneous toxicity has been observed in patients who used Radioderm Spray.