PHOTOTHERAPY, PHOTODYNAMIC THERAPY

ACTIXICAM AFTER PHOTODYNAMIC THERAPY (PDT/DL-PDT) FOR MULTIPLE ACTINIC KERATOSIS LESIONS (THE ATHENA TRIAL): A MULTICENTER RANDOMIZED, PROSPECTIVE PRAGMATIC TRIAL.

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Introduction: Photoprotection strategies are mandatory in subjects with Actinic Keratosis (AK) after specific treatment like Photodynamic Therapy (PDT).

Objective and Materials and Methods: We conducted a randomized,prospective controlled, assessor-masked outcome evaluation, parallel group (1:1), pragmatic study of 6month duration in patients with multiple AK lesions suitable for PDT. The objectives of the study were the evaluation of AK number during the period of treatment/application of the study products, (a piroxicam/50+sunscreen product: ACTX vs. standard photoprotection: SP, SPF 100+) and the Investigator global clinical assessment score (IGA score) after 2-3-6 months after the last PDT session.

Results: Sixty subjects (50 men; mean age 67 years), 34 assigned to treatment with ACTX and 34 to treatment with SP were enrolled in the study. The number of AK lesions present before PDT/DL-PDT was 11.8±5.8 in the ACTX group and 12.4±6.9 in the SP group. In both groups, there was a progressive reduction of AK lesions (-86% and -87% after 2 months and -88% and -83% at month 3 in ACTX in the SP group, respectively). At month 6, AK mean lesion number was 1.8±1.6 in the ACTX and 3.2±2.3 in the SP group; this difference was statistically significant (p=0.03). The IGA score at the end of the study was 3.2 in ACTX and 2.7 in the SP group (p=0.05). The percentage of subjects with an IGA score of 4/3 (very good or good) was 81% in the ACTX and 55% in the SP group (p=0.06).

Discussion: In subjects with AK treated with conventional or daylight PDT, a "medicalized" photoprotection treatment is associated with a favorable clinical outcome with progressive reduction of lesions. In contrast to a standard phoprotection, the use of piroxicam 0.8% and SPF 50 + is associated with a significant greater improvement in clinical evolution of AK lesions.