Tazarote 0.1% Cream Versus Tretinoin 0.05% Emollient Cream in the Treatment of Photodamaged Facial Skin: A Multicenter Double-Blind, Randomized, Parallel-Group Study

INTRODUCTION

Tazarotene 0.1% cream (currently approved by the U.S. Food and Drug Administration) is an effective agent for the mitigation of certain signs of facial photodamage (fine wrinkling, mottling, telangiectasia, and lentigines). The efficacy of tazarotene in this regard is supported by the results of two multicenter, double-blind, vehicle-controlled trials. Only two topical retinoids are approved by the FDA as adjuvant agents for the mitigation of signs of photodamage. Tretinoin 0.05% emollient cream is approved as an adjuvant agent for the mitigation of photodamage in selected patients. The results of these two clinical trials in patients who do not achieve such a benefit using tazarotene cream are presented in this paper. Tazarotene 0.1% cream is approved as an adjuvant agent for the mitigation of fine wrinkling only.

A multicenter double-blind, randomized parallel-group study has been performed to directly compare the efficacy and tolerability of tazarotene 0.1% cream and tretinoin 0.05% emollient cream in the treatment of photodamage. Interim data are now available and are presented in this paper.

METHODS

Study design:

- Multicenter, double-blind, randomized parallel group
- Placebo-controlled

Inclusion criteria:

- Adults with Fitzpatrick type IV
- Facial line wrinkling and/or mottling pigmentation (as least 2/3 of both cheeks
- and at least moderate levels for eyes—over a scale of none, normal, mild, moderate, or severe)

Exclusion criteria:

- Mottled hyperpigmentation, lentigines, fine wrinkling, and tactile roughness (rated on a 5-point scale where 0 none, 1 minimal, 2 mild, 3 moderate, or 4 severe)

Efficacy measures:

- Mean integrated assessment of photodamage
- Fine wrinkling
- Global response assessment of photodamage
- Mottled hyperpigmentation
- Lentigines
- Tactile roughness

Tolerability measures:

- Acne, peeling, redness, dryness, scaling, and burning

RESULTS

- Tazarotene showed more rapid improvements than tretinoin emollient cream, with a photonumeric score (tazarotene) = 0.01 vs. tretinoin emollient cream ≤0.01 (p*0.001 vs. tretinoin emollient cream)
- **Table 1:** Mean scores for lentigines

CONCLUSIONS

The interim data from the trial support the superior efficacy and tolerability of tazarote 0.1% cream versus tretinoin 0.05% emollient cream in the treatment of facial photodamage. Tazarotene is more rapid and effective in improving the appearance of fine wrinkling, mottling, telangiectasia, and lentigines than is tretinoin emollient cream.

REFERENCES


2. Data on file, Allergan Inc.