Evaluating the Clinical and Histologic Effects of Anti-aging Cosmeceuticals

A study now underway seeks to evaluate the efficacy of topical anti-aging formulations.

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early, millions of dollars are spent on over-the-counter (OTC) cosmetic anti-aging products, which claim to reduce wrinkles, fine lines, and sun damage. Very few of these products have been subjected to rigorous controlled trials of efficacy. We are conducting a randomized, single-blind study that aims to examine the effects of six cosmeceutical face creams after daily application for six months, both clinically and histologically, in an effort to refute or to uphold the “anti-aging” claims.

Eligible subjects will be randomized to use one of the six products. Neither the investigator nor the genomic evaluator will know which product the subject has been assigned. At the Day 1 visit after providing informed consent and meeting the inclusion and exclusion criteria, subjects will have a 3mm biopsy taken of the skin behind one ear. Digital photographs will be taken of the subject’s face and crow’s feet area. All subjects will treat their entire face as well as the area behind the one ear from which the biopsy was not taken. In addition, all subjects will be provided with moisturizer control, which they will apply to the entire face and behind both ears, after applying the study product.

After six months of daily use of the randomized study product, subjects will have one 3mm biopsy taken from behind the same ear that was previously biopsied and treated only with the control moisturizer. Another 3mm biopsy will be taken from behind the other ear that was treated with study product. Digital photographs will be repeated. A questionnaire regarding each subject’s opinion of the study product will also be conducted. The biopsies will then be subject to RNA analysis to investigate whether a certain panel of anti-aging markers has been altered from baseline.

STUDY POPULATION
We recruited 95 female subjects. Subjects were 40-75 years old with mild-to-moderate photodamage who have refrained from utilizing antioxidant products on the face for at least six months. Those with rosacea or any other skin disease that could cause an allergic reaction to the study creams were excluded. Additionally, those who were pregnant/lactating, unwilling to avoid excessive sun exposure/tanning beds, unwilling to forgo cosmetic treatments/procedures during the study (botulinum toxin injections, cosmetic filler injections, chemical peels, laser resurfacing, and microdermabrasion) were excluded from enrollment. Quantification assessments were done using a corneometer and vapometer. Additionally, qualitative assessments, which included a Global Photoaging Assessment Scale and a 15-question subject self-assessment questionnaire, were...
completed. Lastly, histologic analysis (via Reverse PCR) of pre- and post-treatment biopsies were executed on all biopsy samples. Study length is six months.

OTC COSMECEUTICALS INVESTIGATED
The six over-the-counter anti-aging cosmeceuticals to be investigated are:
1. Roc Retinol Correxion Deep Wrinkle Filler
2. Olay Professional ProX Deep Wrinkle Treatment
3. Olay Professional ProX Intensive Wrinkle Protocol (includes age repair lotion with sunscreen, wrinkle smoothing cream, deep wrinkle treatment)
4. Aveeno Ageless Vitality Elasticity Recharging System
5. DCL Peptide Plus Treatment Serum
6. MLAB Anti-Aging Treatment Cream

PRELIMINARY UPDATE
Thus far, 95 subjects have been enrolled and 90 subjects have completed the study. Four subjects were terminated from the study early secondary to contact dermatitis reactions experienced from the randomized OTC anti-aging cream.

Adapted from a presentation given at the Cosmetic Surgery Forum 2011 in Las Vegas, NV (cosmeticsurgeryforum.com). This presentation was selected as one of the top 10 resident presentations at the meeting.

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