

Cosmeceutical testing: Ethical and scientific issues

Sir,

We read with interest the article “The effects of a daily facial lotion containing vitamins B3 and E and provitamin B5 on the facial skin of Indian women” by Jerajani *et al.*, published in a recent issue of IJDVL.^[1] Ideally, a cosmeceutical should be clinically tested for efficacy to ensure proven skin benefit and also to substantiate marketing claims.^[2] The authors’ endeavor in this respect is sincerely appreciated. However, few irregularities observed in this study need consideration.

We are given to understand that the principal investigator belongs to a faculty of medical college and the study has been done at a totally different center. Is it ethical for us to use both our credentials (as a consultant and as a faculty) as and in the way we need it. Would it not enhance the credibility of the study if the study was done in an academic institution rather than a private center?

Apart from the principal investigator who is a clinician, all the authors are from the cosmeceutical company. Considering that the product tested was from the same company is it not necessary that the authors should have mentioned any conflict of interest in their study. A double blinding would have mitigated this issue to some extent. A company’s product, when tested for the efficacy, generally requires some remuneration/ assistance to be given to the investigator, patients, and the institution where it is being done. Considering that, the author’s claim of nil source of support in the study requires clarity.

All patients with epidermal pigmentation were included in the study, but various types of epidermal pigmentations, viz., melasma, post inflammatory, post acne, freckles, etc. have not been mentioned and efficacy of the formulation has not been correlated with the same.

Presuming that it is a vehicle controlled study, the composition of control lotion and the sunscreen in

the test lotion is not available in the text. What is the explanation for darkening of the skin observed in the control group? Cosmeceuticals that contain topically applied vitamins have an increasing role in the skin care.^[3] Since the efficacy is tested on the final formulation which, apart from vitamins, contains an unspecified sunscreen as well, it is difficult to separate efficacy of any individual active ingredient.

Therefore, even though the investigators have conducted a study using sophisticated bioengineering tools for assessment, the aforesaid scientific and ethical issues need to be addressed.

Gurcharan Singh, Bhanu Prakash¹

Department of Dermatology and STD, Sri Devaraj Urs Medical College, Tamaka, Kolar, ¹Vydehi Hospital, VIMS & RC, Bangalore, India

Address for correspondence: Dr. Gurcharan Singh, 108, A, Jal Vayu Vihar, Kamanahalli, Bangalore - 560 043, India.
E-mail: gsdrsingh@gmail.com

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