



The truth about CLINICAL STUDIES

It is important to consider the validity of studies and the science behind them reveals **Dr Hans Lautenschläger**.

CLINICAL TESTING FOR skincare products and active ingredients are often looking to prove or disprove a theory or demonstrate the efficacy. Here is a breakdown of the different forms and requirements of clinical testing.

EFFICACY

This is an essential criterion for the selection of pharmaceutical drugs and cosmetic products. Efficacy means that somebody observed or measured a modified condition after applying an active agent or a cream. Since individuals react in very different ways, an isolated observation usually is not sufficient. Similar to a survey, a representative group of individuals has to report on their perceptions or alternatively, an appropriate series of tests are required. Results are then combined and evaluated. If only a small number of cases are available, it is referred to as a practice-based study. Sound studies however imply a high number of cases and statistical evaluation according to approved standards and defined parameters have been followed and met. In this context, statistical significance is calculated to identify objective efficacy in contrast to unavoidable random effects.

To remain with the example active agent and in order to exclude placebo effects, it is advisable to compare conditions both with and without active agents, but also before and after the application. In these test scenarios, neither patients nor treating persons should know who received the active agent and who did not receive it. This procedure is called double blind study.

STUDIES CAN BE UNRELIABLE

The majority of studies are unreliable due to significant facts not being considered or they are perhaps disproved by other studies. Consumers will wonder what is correct now? Within our media-dominated culture, this situation causes confusion since the arguments that are brought forward pro or contra certain results depend on particular interests or alternatively, studies are preferred that fit best the mould of the narrative being told. A more recent example for such kind of a deadlock in studies is the discussion on the harmfulness of aluminum salts used in deodorant and antiperspirant products.

In order to evaluate studies and tests, they have to be accessible for public use. It is a fact though, that the statement "dermatologically tested" is completely useless. Admittedly, it insinuates that a dermatologist was present during testing or that the product was examined according to dermatological criteria however, neither the type of test nor the result has been disclosed in detail. A similar example is the term hypoallergenic, which also is useless without a closer explanation of the conducted tests. Another example in this context are before and after pictures that were taken in non-standard conditions such as lighting, contrasts, background etc. No need to be an expert to recognise manipulations and realise that these are not reliable studies.

ORAL AND TOPICAL APPLICATION

It is also not possible to bring the effects of orally applied substances in line with topically applied substances.

Orally taken evening primrose oil is only effective in a certain percentage of atopic patients with delta-6-desaturase deficit or with a low level of essential fatty acids in general. The dominating topical effect is due to the fact that the contained gamma-linolenic acid is metabolised through the natural 15-lipoxygenase of the skin into anti-inflammatory metabolites. That is the reason why the results of oral and topical studies are diverging and show a broad range of efficacy from non-effective to highly effective substance. It is important to know these underlying conditions in order to understand the effects, to predict them in isolated cases and use them accordingly.

In this context, also the features of oral collagen preparations have to be mentioned. While topical collagens lead to a light tension on the skin surface

through hydrogen bridge linkage and together with a slight bolster effect show a measurable wrinkle reduction, the amino acids of orally taken preparations are partly integrated into the dermal collagen. Studies account on a significant wrinkle reduction in the case of regular oral intake ("wrinkle smoothing from inside"). This effect does not need to be doubted in particular. Nevertheless, it should be noted that the studies only confirm known wisdom that food influences the complexion. It would be interesting to know the respective share of test participants in this study, who more or less avoid meat in their diet.

ALLERGENIC EFFECTS OF SUBSTANCES

Another issue to deal with is reports on the allergenic effects of cosmetic ingredients being communicated, although the quality of components and particularly their purity has changed over the years. This is the case with the frequently used propylene glycol which in the past obviously was fraught with impurities such as the allergenic base component or other impurities forming reactions, both due to its synthesis from propylene via propylene oxide.

Today we can be assured that the substance neither has irritating effects nor is its allergenicity worth mentioning. With regard to health and toxicity, the 100% pure propylene glycol has not a single (!) GHS marking. This is indeed an exceptional case for such kind of ingredient as a pure substance.

STUDY REQUIREMENTS

An important requirement for a relevant result of a study is the selection of test persons. There are also negative examples such as testing anti-ageing creams on the skin of 20 year old test persons or testing moisturisers on a sufficiently hydrated skin. Product comparisons, among others, then show a low efficiency of preparations.

STUDY RELEVANCE

It is no use going as far as to comment on every study with the well-known academic annotation: 'Don't believe in studies that you didn't falsify yourself!' Nevertheless, the examples mentioned above show that the available studies and reports should not induce people to ignore their own common sense.

Furthermore, it can be interesting to know whoever ordered the study. Meanwhile, many publications either conclude with annotations of the authors excluding such kind of cross-linkage or alternatively with disclosures.

Marie von Ebner-Eschenbach coined the following key phrase that also applies to the subject studies: "He who doesn't know a thing has to believe everything." ■



Dr Lautenschläger is an innovator in the field of lipid metabolism disorders, inflammation and circulatory skin conditions. Having published over 200 publications, he is internationally renowned and a world-class leader in cosmetic development and Corneotherapy.
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