

Test Protocol Outline

Photoallergy maximisation - 25 Subject

Objective:

To determine the photoallergenic potential of topically applied product under maximisation conditions.

Experimental Design

100 Healthy volunteers over the age of 18 years will be recruited for this study. The panel will consist of fair skin individuals with skin types I, II or III defined as follows.

Type I - Always burns; never tans (sensitive)

Type II - Always burns easily; tans minimally (sensitive)

Type III - Burns moderately; tans gradually (light brown - normal)

5. Light Source:

The light source employed is a 150W Xenon Arc Solar Simulator 1 (Solar Light Co. Philadelphia, Pennsylvania, Model 12S, Model 14S, or Model 600) having a continuous emission spectrum in the UV-B range from 290 to 320nm will be used. Long ultraviolet light (UV-A, 315-400nm) is obtained by filtering the radiation through a 2mm Schott WG 345 Filter (50% transmission at 345nm) or a 1mm Schott WG 320 Filter.

Method

1. Prior to the testing of sunscreen products, the sensitivity of the unprotected skin of each subject, i.e. the Minimal Erythral Dose (MED), will be determined in seconds, based on the length of exposure with first elicits a slight reddening of the skin, as observed 16-24 hours following exposure.

2. Duplicate test areas (2.5 x 2.5 cm) to which 62.5ul of the test substance will be evenly applied (at a density of 10mg/cm²) will be delineated on the subject's back. Sites will be covered with 2cm x 2cm Parke-Davis Rendi Bandage occlusive patches or the equivalent. After 24 hours the test sites will be wiped dry with gauze and one set will be exposed to 3 MED's of solar simulating radiation while the alternate set will again be left nonirradiated. This sequence will be repeated for a total of 6 exposures over the course of three weeks. Concurrently five sites will be selected as controls according to the following scheme:

- a. normal intact skin untreated - no exposure
- b. normal intact skin untreated - irradiated with 4.0joules/cm² UV-A exposure
- c. patch materials only - no product - no exposure
- d. patch materials with 4.0joules/cm² UV-A exposure only.
- e. Hydrophilic Ointment USP - patched nonirradiated
- f. Hydrophilic Ointment USP - patched and irradiated

The patching regimen for the controls follows the same scheme as test products with the exception of the UV-A irradiated sham-control (c)

3. Subjects will be challenged 10-14 days after the final induction exposure. Similar occlusive applications will be made for 24 hours to a previously unexposed, untreated, area of normal skin. The sites will then be irradiated with 10.0 joules/cm² of UV-A radiation. Reactions will be scored in 48 and 72 hours post challenge irradiation. The subjects will be asked to report any reactions which might occur after the final challenge patch reading.

References

AMA - Standard Operating Procedures, Clinical Trials, Photoallergy Maximization Test on Human Subjects.