Safety and efficacy in the use of a micronutrient-containing barrier product in the management of damaged skin in the diaper area of infants in the NICU

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INTRODUCTION AND CLINICAL PROBLEM

Infants in a typical neonatal intensive care unit have cleansing needs that require the repetitive use of bathing and cleansing products. Dry and inflamed skin is a common problem, primarily because neonatal skin is not fully developed. The perineal areas in infants may be particularly prone to skin damage, usually presenting as erythema in various degrees. Barrier creams are often used to manage skin damage. Most barrier formulations derive their protective properties from petrolatum, which creates a hydrophobic layer on the skin. State of the art formulations also contain silicones and zinc oxide, which are used as medical grade viscosity enhancers to retain product better at the application site. However, there is little published data on the use of barrier formulations on infant skin. This IRB-approved longitudinal study aims to further demonstrate product safety and quantitatively model the ability of a micronutrient barrier containing a silicone and zinc oxide combination to protect and manage damaged neonatal perineal skin post-cleansing.

METHODS

A convenience sample of 10 neonates, average weight 2.8 kg, average age 6.5 weeks, were studied for the period of their confinement in the NICU setting, ranging from 2 to 14 days. Perineal skin was assessed at each diaper change and soiling event, and barrier product* was applied post-washing** if the erythema score was level 1 or above.

Data collection of erythema score and pain level was conducted by the managing clinicians on standardized charts. The pain level was conducted by the managing clinicians on standardized charts. The outcome measures were determined by clinicians on standardized charts. The pain level was conducted by the managing clinicians on standardized charts. The outcome measures were determined by clinicians on standardized charts. The pain level was conducted by the managing clinicians on standardized charts. The outcome measures were determined by clinicians on standardized charts. The pain level was conducted by the managing clinicians on standardized charts. The outcome measures were determined by clinicians on standardized charts.

SUBJECT DEMOGRAPHICS

10 Subjects Enrolled
- 3 Males, 7 Females
- 90% Hispanic, 10% Caucasian
- Average body Weight: 2.8 kg (6.2 lb)
- Average Age: 6.5 wks

RESULTS

Out of the 1216 applications of cleanser and 335 applications of barrier cream, no adverse events were reported from exposure of neonatal skin to the study products. One subject was withdrawn from the study due to worsening skin condition unrelated to test product application. Out of the 9 subjects who completed the study, 6 experienced return to normal skin conditions within 6 days of initiating barrier treatment. In only one case did barrier use continue for 14 days without resolution of erythema. Barrier treatment ranged from 1 to 14 days, with a mean of 4.2 days (SD = 3.9).

In order to quantify the efficacy of the micronutrient containing barrier in resolving erythema at level 1 or above, data points for each individual case of use were fit to a linear regression model. Day 0 was defined as the day on which barrier use commenced, and erythema scores were plotted to the day after the last use of barrier cream. Time in days was plotted on the x axis, and erythema score was plotted on the y axis. The slope of the fitted graph reflects, on average, the amount by which the erythema score is reduced with each day of treatment. An average of the slopes of each case of use produces the equation y = -0.53x + 4 where each day of barrier treatment reduces the erythema score by approximately half a level. Thus, it takes on average 1.9 days to bring the erythema score down by 1 level.

REFERENCES


*Remedy® Phytoplex Z-GUARD. **Remedy® Phytoplex Hydrating Cleansing Foam. Remedy is a registered trademark and Phytoplex, Z-Guard are trademarks of Medline Industries, Inc. Mundelein, IL.