JOHNSON & JOHNSON CONSUMER INC.

SUMMARY CLINICAL STUDY REPORT

PROTOCOL TITLE:	A Single Center, Five Week, Evaluator Blinded, Clinical Trial Evaluating Two Cleansing and/or Moisturizing Regimens on the Skin of Healthy Infants Using Clinical, Instrumental, D-Squame® Tape, Microbiome and Parental Assessments
PROTOCOL NUMBER:	CO-170929100633-SBCT Amendment 2, Version 4.0 dated, 22 Jan 2018
SPONSOR:	Johnson & Johnson Consumer Inc. 199 Grandview Road, Skillman, NJ 08558 USA
STUDY SITE:	[redacted] JOHNSON & JOHNSON Consumer Experience Center (CxC) 199 Grandview Road Skillman, NJ 08558 USA
PRINCIPAL INVESTIGATOR: [redacted]	[redacted]
INVESTIGATIONAL STUDY MATERIALS	See table below
STUDY INITIATION DATE (First Subject First Visit):	10-JAN-2018
STUDY COMPLETION DATE (Last Subject Completed):	11-MAY-2018
DATA ANALYSIS and REPORT WRITING SERVICES:	[redacted] Thomas J. Stephens & Associates, Inc. Texas Research Center 1801 North Glenville Drive, Suite 200 Richardson, TX 75081

Identification	Formula number	Product type	Group Designation
Baby Cleanser/Shampoo	[redacted]	Investigational Product (IP)	Group 1 and Group 2
Baby Lotion	[redacted]	IP	Group 2
Commercial Baby Wash	[redacted]	Auxiliary Product	N/A

SPONSOR REVIEW AND APPROVAL:	**Name** / **Signature and date:** [redacted] / [redacted] [redacted] **Study Director** / [redacted]

The principles of the International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP E6 (R2)) were applied to this study.

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PURPOSE

Skin cleansing has been demonstrated as a simple strategy to help keep skin healthy. There are many types of cleansing and moisturizing routines that have been shown to have different effects on the skin barrier such as reducing sebum and exogenous contaminants, controlling odors, and affecting the skin microbiome.[1] A previous study in an adult population showed that use of a mild surfactant cleanser had less of an impact on the skin barrier than a liquid castile soap (data on file).[2] Because infant skin differs from an adult's in structure, function, and composition[3], cleanser and/or lotion regimens may impact the skin barrier of infants differently.

There is very little information in the literature on how the use of product regimens impacts the cutaneous microbiome and skin physiology of adults[1] and even less about how it impacts the skin of children.

This single center, randomized, evaluator-blind, 5-week clinical trial was conducted for JOHNSON & JOHNSON Consumer Inc. to assess the impact of 2 skincare regimens on the cutaneous microbiome and skin physiology of healthy male and female infants ages 3-6 months using clinical, instrumental, D-Squame® tape, microbiome, and parental assessments over the course of a 4-week treatment period followed by a 3- to 5-day regression period. The investigational products (IPs) are a baby wash and a baby lotion (both cosmetic body products). The auxiliary product is a commercially available cosmetic baby body wash.

STUDY DESIGN SUMMARY

A total of 30 subjects completed study participation, with 32 subjects included in the full analysis set (FAS) population. Within the FAS population, there were 16 subjects in group 1 (cleansing regimen: Baby Cleanser/Shampoo) and 16 subjects in group 2 (cleansing and moisturizing regimen: Baby Cleanser/Shampoo and Baby Lotion).

Subjects were assigned to group 1 or group 2 in accordance with a predetermined randomization. Separate randomizations for group assignment were used for male and female subjects. A secondary randomization was generated to indicate the dorsal forearm for microbiome and D-Squame® samples collection. Corneometer and skin pH measurements were collected from the opposite dorsal forearm.

Parents/legally acceptable representatives (LARs) were provided with the auxiliary product (Commercial Baby Wash) at visit 1 (screening) and visit 4 (day 28). Parents/LARs used the auxiliary product on the subjects at least 3 times during the washout period (for 7 days prior to baseline, between screening and baseline/day 0) and at least 3 times during the regression period (for 3-5 days, between day 28 and regression day 3-5), as directed.

During the 4-week usage period, parents/LARs used the IPs as directed. For group 1, parents/LARs used the Baby Cleanser/Shampoo on the subjects at least 3 times per week (with a maximum of once per day). For group 2, parents/LARs used the Baby Cleanser/ Shampoo on the subjects at least 3 times per week (with a maximum of once per day) and applied Baby Lotion on the subjects

at least once per day (with a maximum of twice per day). Parents/LARs for subjects in group 2 performed the first application of the lotion in the study site after completion of baseline evaluations.

Clinical evaluations were conducted at visit 2 (baseline/day 0 and 5-15 minutes post-application [group 2 only]), visit 3 (day 14), visit 4 (day 28), and visit 5 (regression day 3-5).

A paper "standardized anatomical drawing" of test sites was used for each subject to indicate on which forearm Microbiome and D-Squame® tape sampling were performed; Corneometer measurements and Skin pH measurements were performed on the opposite forearm, at separate locations.

Subjects participated in the following procedures at each time point (unless otherwise indicated):

• Skin Hydration (Corneometer) Measurements: Three (3) consecutive readings were obtained within each test site on the subject's dorsal forearm using Corneometer® CM825 (Courage-Khazaka Electronic GmbH) to measure skin moisturization. The measurements were collected from the opposite dorsal forearm used for microbiome sampling.

• Skin pH Measurements: Five (5) consecutive readings were obtained within each test site on the subject's dorsal forearm using Skin-pH-Meter® (PH 905, Courage & Khazaka, Germany) to measure the pH-level on the skin surface. The measurements were collected from the opposite dorsal forearm used for microbiome sampling.

• Clinical Assessment Evaluations: At baseline/day 0, day 14, day 28, and regression day 3-5, the PI or designee assessed for dryness, redness/erythema, rash/irritation, tactile roughness and total score of objective irritation on each subject's arms, legs, and torso (which included chest, back and diaper area). Total score of objective irritation for each of the 3 body sites was calculated.

• Parent/LAR Assessment: At baseline/day 0, day 14, day 28, and regression day 3-5, parents/LARs provided an overall assessment of the subject's skin. At regression day 3-5, parents/LARs also completed a parental questionnaire.

• D-Squame® Samples: At baseline/day 0 and day 28, 2 D-Squame® tape samples were collected on the dorsal forearm, adjacent to the site used for microbial samples collection, using D-Squame® Standard Sampling Discs (CuDerm Corporation, Dallas, TX). Samples were sent to the lab for analysis as per protocol specification. The results were analyzed and summarized in a supplemental report to the full clinical study report.

• Microbiome Samples: At baseline/day 0, day 14, day 28, and regression day 3-5, surface skin flora samples were collected from each subject's forehead, forearm, and buttock using a non-invasive swab technique. Each subject had 2 swabs collected from each body site for a total of 6 samples at each time point. The samples on the forearm and buttock were collected from the same side of the body (right or left). Samples were sent to an independent external researcher/laboratory

for DNA extraction and pyrosequencing as per protocol specifications. The results were analyzed and summarized in a supplemental report to the full clinical study report.

RESULTS AND FINDINGS

Primary Outcomes:

Skin Hydration
Results of the Corneometer measurements showed a statistically significant improvement in skin hydration at 5-15 minutes post-application for group 2 (cleansing and moisturizing regimen) when compared with baseline (note: group 1 was not assessed at this timepoint, per protocol). This was expected due to this timepoint being associated with the first application of lotion. After regressing for 3-5 days, there was a statistically significant worsening in skin hydration for group 2 (cleansing and moisturizing regimen) when compared with day 28. This would be expected due to the discontinuation of lotion use during the egression period.

Skin pH
Results of the skin pH measurements showed a statistically significant increase in skin pH at regression day 3-5 for group 1 (cleansing regimen) and at 5-15 minutes post-application and day 14 for group 2 (cleansing and moisturizing regimen) when compared with baseline. After regressing for 3-5 days, there were no statistically significant changes in skin pH values for either group when compared with day 28. Results of the mean skin pH measurements remained within the mildly acidic range (4.0-6.0) throughout the course of the study.

Secondary Outcomes:

Clinical Evaluation
Results of the clinical assessment showed no statistically significant changes for dryness, redness/ erythema, rash/irritation, tactile roughness, and total score of objective irritation on the arms, legs, and torso, and for assessment of skin looks [irritation, dryness], skin feels [roughness, softness], and overall skin appearance in both groups at day 14, day 28, and regression day 3-5 when compared with baseline and after regressing for 3-5 days when compared with day 28.

Overall Skin Appearance by Parent/LAR Assessment
Results of the parent/LAR assessment showed a statistically significant worsening in skin looks (irritation) at day 28 for group 1 (cleansing regimen) and a statistically significant improvement in skin feels (softness) at day 14 and regression day 3-5 for group 2 (cleansing and moisturizing regimen) when compared with baseline. After regressing for 3-5 days, there were no statistically significant changes in scores for parent/LAR assessment of skin looks (irritation, dryness), skin feels (roughness, softness), and overall skin appearance for either group when compared with day 28. Treatment comparisons for the usage period through the end of regression period indicated a statistically significant difference in the parent/LAR assessment in favor of group 2 at day 28 for skin looks (irritation) and at regression day 3-5 for skin feels (softness). Treatment comparisons for the regression period indicated a statistically significant difference in the parent/LAR assessment in favor of group 1 (cleansing regimen) at regression day 3-5 compared with day 28

for skin looks (irritation) where 40% of subjects improved in group 1 (0.0% for group 2) and 13.3% of subjects worsened in both groups.

D-Squame® Samples

The metabolomic profile of the skin surface was assessed on skin tape samples collected at baseline and at day 28 of product use. Group 1 (wash only) showed overall an increase in amino acid content, whereas group 2 (wash and lotion) showed a moderate reduction in amino acid content. The increase of amino acid content may be considered as a response to the use of the mild cleanser and this response was ameliorated or even reversed by the use of lotion, indicating the soothing effect of the lotion. Moreover, group 2 that received the lotion treatment together with the wash showed an overall increase in lipid metabolism and in particularly increased production of certain ceramide moieties. An increased production of lipids and notably ceramides are expected to confer a benefit in supporting the skin barrier integrity.

Microbial Richness and Diversity

Microbial diversity and richness were measured at baseline, day 14 and day 28 of product use, and after 3-5 days of regression. While microbial diversity was maintained with both regimens, there was a statistically significant increase in microbial richness with emollient use, suggesting that emollients may help improve microbial community richness, as well as overall skin barrier integrity and skin health early in life.

OVERALL CONCLUSIONS

Overall results of this single center, randomized, evaluator-blind, 5-week clinical trial indicate that the Sponsor's 2 skincare regimens (group 1: cleansing regimen [Baby Cleanser/Shampoo] and group 2: cleansing and moisturizing regimen [Baby Cleanser/Shampoo and Baby Lotion]) were well tolerated when used on male and female infants ages 3-6 months over the course of 4 weeks followed by 3-5 days of regression.