A Single-Center, Four Week Usage Clinical Study to Evaluate the Tolerance and Efficacy of a Whole-Body Balm on Newborn Babies

Prepared for:

Johnson & Johnson Consumer Inc.

Protocol Number: CCSSKB005124

Study Conducted by CenExel JBR
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SGS Study Reference Number: C22-D047N

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GENERAL INFORMATION

Testing Information

Protocol Title:	A Single-Center, Four Week Usage Clinical Study to Evaluate the Tolerance and Efficacy of a Whole-Body Balm on Newborn Babies
Protocol Number:	CCSSKB005124
Investigational Product (IP):	Balm, [redacted]
Auxiliary Product:	Wash & Shampoo, [redacted]
Study Start Date:	28 Apr 2023
Study End Date:	06 Oct 2023

Study Site Information

Study Site:	Site Number: NA033 CenExel JBR 650 East 4500 South Suite #100 Salt Lake City, UT 84107
Principal Investigator (PI):	Todd Bertoch, MD
Study Pediatrician:	Gary Schlichter, MD
Sub-Investigators:	Nancy Veit, NP Seth Grisham, PA Ryan Black, MD

Sponsor Information

Sponsor:	Johnson & Johnson Consumer Inc. 199 Grandview Road Skillman, NJ 08558
Study Manager:	Gboyega Adenaike
Study Directors:	Gabrielle Kosmoski Victoria Aleles
Department Head:	[redacted]
Designated Physician Representative:	[redacted]

Data Analysis and Report Writing Information

SGS Study Reference Number:	C22-D047N
Data Analysis and Report Writing Services:	SGS Dallas Research Center 1801 North Glenville Drive, Suite 200 Richardson, TX 75081

SUMMARY

Tolerability studies, also known as Safety in Use Tests (SIUTs), assess the tolerance of topical products under normal use or reasonably predictable conditions. These studies are conducted to ensure topical tolerance of the products, considering clinical and parent/legal guardian assessment under these conditions.

This single-center, monadic, 4-week, clinical trial was conducted for Johnson & Johnson Consumer Inc. to evaluate the skin tolerance (assessed by clinical grading and parental assessment), instrumental efficacy (assessed by Corneometer and Vapometer), and perceived product efficacy (assessed by parental questionnaire) of a whole-body balm on newborn subjects (0-3 months old).

The exploratory objective of this study was to assess the absorption/desorption of the skin of newborn subjects (assessed by Novameter).

A total of 30 subject pairs (parent subject and newborn subject) were enrolled in the study and 28 subject pairs completed study participation. All enrolled subject pairs were included in the intent-to-treat (ITT) population, defined as all subject pairs who used the IP and completed baseline and at least one post-baseline evaluation. All enrolled subject pairs were included in the adverse event (AE) analysis set, defined as all subject pairs whose parent subject signed the Informed Consent Document (ICD).

At Visit 1 (Screening/Baseline/Day 0), the subject pairs were provided the IP (Balm, [redacted]) and the auxiliary product (Wash & Shampoo, [redacted] to use for the duration of the study. The parent subjects were instructed to apply the IP (Balm, [redacted] on the newborn subject's whole body (excluding the mouth, eyes, diaper area, and scalp) twice per day (morning and evening), and to cleanse the newborn subject using the auxiliary product (Wash & Shampoo, [redacted]) at least once per week and no more than 3 times per week, according to the detailed product instructions below:

- Balm: Apply enough of the balm in your hand to cover your newborn baby's entire body (while avoiding the mouth, eyes, diaper area, and scalp), and gently massage onto the skin until the balm is fully absorbed. On days that you bathe your newborn baby, apply the balm after patting your newborn baby's skin completely dry.

- Wash & Shampoo: Wet your newborn baby's body and scalp with warm water (approximately 100 degrees Fahrenheit). Dispense a small amount of the wash & shampoo onto a wet washcloth or hand, and lather. Gently cleanse your newborn baby's entire body, face (avoiding the eyes), scalp, and hair, and then rinse and pat the newborn baby's skin completely dry.

Clinical evaluations were conducted at Visit 1 (Screening/Baseline/Day 0), Visit 2 (Day 7), and Visit 3 (Day 28). One (1) test site was marked on the newborn subject's right volar forearm using a template and an indelible, skin-safe marker. The test site was 2.5 cm x 2.5 cm and placed at least 2.5 cm from the newborn subject's wrist. Subject pairs participated in the following procedures at the indicated time points:

- Clinical Evaluation of Tolerance
  At Visit 1 (Screening/Baseline/Day 0), Visit 2 (Day 7), and Visit 3 (Day 28), the PI or a trained designee assessed the newborn subject's face, arms (right and left together), legs (right and left together), and torso (chest and back together) separately for dryness, erythema, rash/irritation, and tactile roughness.

- Parental Evaluation of Tolerance
  At Visit 1 (Screening/Baseline/Day 0), Visit 2 (Day 7), and Visit 3 (Day 28), the PI or a trained designee asked the parent subject to assess their newborn subject's face, arms (right and left together), legs (right and left together), and torso (chest and back together) separately for burning/stinging and itching, and recorded the parent subject's responses.

SUMMARY (continued)

- Skin Capacitance Measurements
  At Visit 1 (Screening/Baseline/Day 0), Visit 2 (Day 7), and Visit 3 (Day 28), 5 measurements were taken from adjacent locations within the test site on the newborn subjects' right volar forearm using Corneometer (Courage + Khazaka electronic GmbH, Koln, Germany) to measure the moisture content in the stratum corneum by an electrical capacitance method.

- Transepidermal Water Loss (TEWL) Measurements
  At Visit 1 (Screening/Baseline/Day 0), Visit 2 (Day 7), and Visit 3 (Day 28), 1 measurement was taken from the center of the test site on the newborn subjects' right volar forearm using a Delfin VapoMeter (Delfin Technologies Ltd., Kupio Finland) to measure the transepidermal water loss (TEWL).

- Absorption/Desorption Measurements
  At Visit 1 (Screening/Baseline/Day 0), measurements were taken from the center of the test site on the newborn subjects' right volar forearm using Novameter DPM 9300 (NOVA Technology Corp., Gloucester, Massachusetts) to obtain an indication of the skin's barrier properties by determining the hygroscopicity of the skin, or its capacity to take up water (absorption), its water holding capacity (ability to hold onto exogenously applied water), or the ability for the skin to retain water (desorption).

- Parental Questionnaire
  At Visit 3 (Day 28), parent subjects completed the parental questionnaire regarding perceptual product efficacy.

Overall Conclusions

Overall results from this single-center, monadic, 4-week, clinical trial indicate that the Sponsor's IP (Balm, [redacted]) was well tolerated (as assessed by clinical grading and parental assessment) and effective (as assessed by skin capacitance measurements, TEWL measurements, and parental questionnaire), when used on newborn subjects (0-3 months old), under the conditions of this test.

Analysis of the clinical evaluation of tolerance showed no statistically significant ($P \leq 0.05$) change (increase or decrease) in scores for any parameter (dryness, erythema, rash/irritation, or tactile roughness) at any location (face, arms, legs, torso, or global body) at Visit 2 (Day 7) or Visit 3 (Day 28) when compared with Visit 1 (Baseline/Day 0).

Analysis of the parental evaluation of tolerance showed no statistically significant ($P \leq 0.05$) change (increase or decrease) in scores for any parameter (burning/stinging or itching) at any location (face, arms, legs, torso, or global body) at Visit 2 (Day 7) or Visit 3 (Day 28) when compared with Visit 1 (Baseline/Day 0).

Analysis of the skin capacitance measurements showed a statistically significant ($P \leq 0.05$) increase in values (improvement in skin hydration) at Visit 2 (Day 7) and Visit 3 (Day 28) when compared with Visit 1 (Baseline/Day 0).

Analysis of the TEWL measurements showed no statistically significant ($P \leq 0.05$) change (increase or decrease) in values at Visit 2 (Day 7) or Visit 3 (Day 28) when compared with Visit 1 (Baseline/Day 0).

SUMMARY (continued)

Overall Conclusions (continued)

Analysis of the parental questionnaire completed at Visit 3 (Day 28) showed that a statistically significantly ($P \leq 0.05$) greater proportion of parent subjects selected favorable responses (strongly agree and somewhat agree) compared to the proportion who selected unfavorable responses (strongly disagree and somewhat disagree) to 17 out of 18 inquiries (as specified below), indicating positive parental perceptions of the IP.

- This Balm soothes my newborn's skin.
- This Balm nourishes my newborn's skin.
- This Balm comforts my newborn's skin.
- This Balm is gentle enough for daily use.
- This Balm leaves my newborn's skin moisturized.
- This Balm leaves my newborn's skin looking healthier.
- This Balm leaves my newborn's skin feeling healthier.
- This Balm leaves my newborn's skin feeling soft and smooth.
- This Balm hydrates my newborn's skin and leaves it feeling moist.
- This Balm leaves my newborn's skin with a healthy glow.
- This Balm is easy to apply to my newborn's skin.
- I feel that my newborn's skin feels less dry.
- This Balm nourishes my newborn's dry skin.
- This Balm forms a protective layer on my newborn's skin.
- This Balm protects my newborn's sensitive skin barrier.
- This Balm provides gentle hydration for my newborn's skin.
- This Balm is suitable for all skin tones/types.

Descriptive statistics for the absorption/desorption rate of individual sub-intervals, sum of sub-intervals, and water holding capacity are shown in Table 16.

Adverse Events (AEs)

The following non-serious AEs were reported/observed during the study:

- Subject ID 1020: Moderate back ache in the lower back. AE was not related to the study.
- Subject ID 2016: Mild rash on the torso. AE had a possible relationship to the study.
- Subject ID 2017: Mild rash on the torso. AE had a possible relationship to the study.
- Subject ID 2020: Mild teething pain. AE was not related to the study.
- Subject ID 2021: Mild tactile skin roughness on the torso and legs. AE had a possible relationship to the study.
- Subject ID 2022: Mild rash on the lower back. AE had a probable relationship to the study.
- Subject ID 2023: Mild tactile skin roughness on the arms, torso, and legs. Mild erythema on the face, arms, legs, and torso. Both AEs had a possible relationship to the study.
- Subject ID 2028: Mild baby acne on the face. AE had a doubtful relationship to the study.
- Subject ID 2030: Mild pinpoint rash on the lower half of back. AE had a probable relationship to the study.
- Subject ID 2031: Mild baby acne on the face. Mild constipation. Both AEs were not related to the study.

No serious AEs (SAEs), other significant AEs, and/or exposure in utero (EIU) were reported/observed during the course of the study.

Disclaimer

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