JOHNSON & JOHNSON CONSUMER INC.

SUMMARY CLINICAL STUDY REPORT

PROTOCOL TITLE:	A Randomized Controlled Trial of Gentle Touch/Early Massage with a New Wash and Lotion Regimen for Improved Skin Barrier Strength, Parental Bonding, and Physical Development in Newborn Babies: The Barrier Optimizing skincare for Newborn Development (BOND) trial
PROTOCOL NUMBER:	CO-1610 1411 2628-SBCT Final v 1.0, 14MAR2017 Amendment v 2.0, 31MAR2017 Amendment v 3.0, 21APR2017 Amendment v 4.0, 21JUL2017 Amendment v 5.0, 01OCT2018 Amendment v 6.0, 14JUN2019
DOCUMENT DATE:	08NOV2023
SPONSOR:	Johnson & Johnson Consumer Inc.
STUDY SITE:	Sheffield Dermatology Research Skin Barrier Facility, The Royal Hallamshire Hospital (K-Floor), B Road, Sheffield S10 2RX
PRINCIPAL INVESTIGATOR:	Prof. Michael J Cork BSc. MB. PhD. FRCP
KEY STAFF:	*Site* Prof. Michael J Cork BSc. MB. PhD. FRCP (Principal Investigator) Dr. Simon G Danby BSc (Hon), PhD (Sub Investigator) Dr. Shatha Shibib (Sub Investigator) Dame Professor Tina Lavender PhD, MSc, RM, RGN (Sub Investigator) *Sponsor* Designated Physician Representative: Zarine Simonyan, MD Study Director: Gabrielle Kosmoski Study Manager: Heather Smith Department Head: Karen Meyer
STUDY INITIATION DATE (First Subject First Visit):	04 Dec 2018
STUDY COMPLETION DATE (Last Subject Completed):	05 Jun 2020
SITE APPROVAL:	See trial master file for final clinical study report and approvals
SPONSOR REVIEW AND APPROVAL:	See trial master file for final clinical study report and approvals

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

INTRODUCTION	The skin of a newborn has a sensitive skin barrier relative to an older child and an adult. Newborn's skin, for example, is extremely vulnerable to damage by environmental agents such as harsh detergents, some topical oils, and other irritant chemicals. Evolving perspectives on barrier dysfunction in newborn babies has led to the idea that there may be a window of opportunity in the first few months of a newborn's life to change the environmental agents that their skin is exposed to in order to maximize skin health. These environmental changes could involve the use of optimally formulated wash products and emollients, as well as the removal of all other irritant substances that could damage the skin barrier. Further research is required to identify skincare practices that are harmful and those that are positive, and to ultimately ascertain what the optimum skincare routine should be. An important skincare strategy is to identify an appropriate regimen (use of topical emollients and wash products) that will be used to maintain healthy skin in the future.
OBJECTIVE	The objective of this study was to determine whether a wash and lotion regimen used for 12 weeks can strengthen the skin barrier in newborns when compared to standard skincare practices without massage.
STUDY DESIGN	Single center, evaluator blind, randomized, controlled trial.
SUBJECT INFORMATION	The complete eligibility criteria for this study were followed as defined in the study protocol referenced on page 1 of this report.
INVESTIGATIONAL STUDY MATERIAL	The investigational products were marketed cosmetics: Baby Wash & Shampoo (F# 13217-070) Baby Lotion (F# 13217-071) Alternative Baby Wash & Shampoo (GTIN/UPC # 5011451106260)
DOSE AND MODE OF APPLICATION	<u>Group 1:</u> Baby Wash & Shampoo and Baby Lotion (with massage) Baby Wash & Shampoo (F# 13217-070) – This product was used at least 3 times per week for 12 weeks to cleanse the child's hair, entire body, and face, avoiding the eyes. Baby Lotion (F# 13217-071) - This product was used once daily (immediately following bathing on bath days). <u>Group 2:</u> Baby Wash & Shampoo (no massage) Baby Wash & Shampoo (F# 13217-070) – This product was used at least 3 times per week to cleanse the child's hair, entire body, and face, avoiding the eyes. <u>Group 3:</u> Alternative Baby Wash & Shampoo (no massage) Baby Wash & Shampoo (GTIN / UPC # 5011451106260) – This product was used at least 3 times per week to cleanse the child's hair, entire body, and face, avoiding the eyes.
METHODOLOGY	Efficacy to strengthen the skin barrier was measured by Trans Epidermal Water Loss (TEWL) and Stratum Corneum Hydration. The primary analyses of TEWL and stratum corneum hydration (corneometer) used a two-sample t-test to compare:

	-Arm 1 (Baby wash & shampoo plus baby lotion with massage) to Arm 2 (Baby wash & shampoo without lotion/massage) -Arm 1 (Baby wash & shampoo plus baby lotion with massage) to Arm 3 (alternative wash and shampoo) Product tolerance will be measured by clinical assessments of the skin and adverse events.
MEASUREMENT AND/OR EVALUATION SCHEDULE	TEWL and stratum corneum hydration were collected at Baseline Visit and Week 12 Visit. Safety Events were captured throughout the study duration.
RESEARCH ETHICS COMMITTEE (REC)	<u>This study was reviewed and approved by the following</u>: Research Ethics Committee Yorkshire and the Humber – Sheffield
SAFETY AND ADVERSE EVENTS	All Adverse Events (AEs/SAEs) were collected regardless of causal relationship to the subject's participation in the study. The information was collected/reported within the reporting timelines specified in the protocol.
MONITORING, QUALITY CONTROL, AND QUALITY ASSURANCE	The study monitoring was conducted as per the Sponsor´s requirements. The Study Site was/is subject to review by the REC, to quality assurance audits performed by the Sponsor, and/or to inspection by appropriate regulatory authorities. See trial master file for final monitoring reports.
OVERALL CONCLUSIONS	**Efficacy Results**: 51 mothers and babies were randomised of which 47 completed the skin care regimens. Stratum corneum hydration increased by 22.9±10.45 arbitrary units from baseline (capacitance) to 12 weeks in the group using the test wash and lotion (Arm 1) compared to an increase of 20.7±9.36 using the test wash only (Arm 2) and 15.6±5.86 using the reference wash product (Arm 3). The test wash and lotion (Arm 1) was significantly more hydrating than the reference wash alone (Arm 3) (Mean difference -7.3 (95%CI -13.97, -0.73). No significant differences in hydration after 12 week treatment were found comparing the test wash and lotion (Arm 1) with the test wash alone (Arm 2). TEWL increased, from baseline to week 12, at test sites treated with test wash (Arm 2) and test wash and lotion (Arm 1), with an increase of 9.2±18.45 g/m²/h and 9.8±20.96 g/m²/h, respectively. There were no significant differences in the change in TEWL from baseline to Week 12 between any of the arms. Spectroscopic analysis revealed concomitant changes in the level of water and water-binding compounds in the stratum corneum. **Safety Results**: All products were well tolerated. There were 152 TEAEs of mainly mild intensity reported possibly related to the study products, occurring roughly equally between the products used and consistent with expectations for this type of intervention in this population. **Conclusion**: The combined wash and lotion regimen (Arm 1) provided hydration compared to the reference wash-only regimen (Arm 3). No significant differences between test wash and lotion (Arm 1) and test wash only (Arm 2), were found for TEWL or hydration.

[Remainder of Page Intentionally Left Blank]

Disclaimer

Information in this posting shall not be considered to be a claim for any product, whether marketed or under development. In case of a marketed product, some of the information in this posting may differ from, or not be included in, the approved labeling for the product. Please refer to the full prescribing information for indications and proper use of the product.