

# Evaluation of the efficacy and safety of “Nourishing Baby Oil” in infantile xerosis

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## Abstract

*Infantile dry skin (xerosis) is a common skin condition, which is associated with a defect in skin barrier function. Oil massaging benefits infants in many ways, and also helps in maintaining the skin moisture equilibrium. The “Nourishing Baby Oil” is a polyherbal formulation recommended for the prevention and management of infantile dry skin. This study was planned to evaluate the efficacy and safety of “Nourishing Baby Oil” in infants, between 1 to 12 months of age.*

*This was a prospective, open, phase III clinical trial, conducted as per the GCP guidelines. Babies between the age of 1 to 12 months, born at term with a birth weight of more than 2500 g, having appropriate gain in weight, length and head circumference and a normal psychomotor development, and whose parents were willing to give written consent were included in the study. All the parents were advised to apply a small amount of “Nourishing Baby Oil” using firm but gentle strokes all over the baby, which was followed by gentle massage. The signs and symptoms of immediate skin irritation and delayed hypersensitivity reactions were evaluated as per the standardized guidelines. The parents were instructed to visit the “Well Baby Clinic” of the Department of Pediatrics, Medical College and Hospital, Kolkata, with their infants on the 7<sup>th</sup> and 14<sup>th</sup> day of application. All the adverse events, either reported or observed by the parents were recorded with information about onset, severity, duration and site of the adverse reaction.*

*This study observed a significant reduction in the skin dryness, improvement in the softness of the skin, and skin glow. It was also noticed that the “Nourishing Baby Oil” was absorbed rapidly, leaving the baby skin soft with a natural, healthy glow and without any greasy after-feel. These beneficial effects might have been due to the synergistic actions (skin nourishing, emollient, moisturizing, soothing, antimicrobial, anti-inflammatory, and antioxidant) of its ingredients.*

**Abbreviations:** GCP: Good clinical practice

## Introduction

The infantile skin is delicate and is at high risk of dryness. Infantile dry skin (xerosis) is a common skin condition characterized by dry, rough and itchy skin, which is associated with a defect in skin barrier function. The skin needs moisture to stay smooth and supple in order to perform its normal physiological functions effectively. However, retaining moisture is especially difficult in winter. Simple daily routines such as bathing and towel drying, actually remove moisture from the skin. Bathing coats the skin with moisturize temporarily, but it removes the skin's oily lipid layer and in the long run causes more moisture loss than gain.

Oil massaging benefits infants, as oil massage stimulates all the senses of the baby and establishes a more intense visual and tactile communication with the massages. Baby massage aids growth and development, builds trust and intimacy, creates the foundation for communication that lasts long after infancy ends, develops closeness, enhances the bond between the mother and the child, facilitates early infant communication, gives the mother the confidence in her ability to handle and comfort the baby, helps the baby to sleep more soundly and for longer, and helps premature babies to gain weight faster.

The “Nourishing Baby Oil” is a polyherbal formulation recommended for the prevention and management of infantile dry skin. The “Nourishing Baby Oil” contains the oil of *Olea europaea*, and the oil extracts of *Sida cordifolia*, *Withania somnifera*, *Vetiveria zizanioides* and *Aloe vera*, and this study was planned to evaluate the efficacy and safety of “Nourishing Baby Oil” in infantile dry skin.

### **Aim of the study**

This study was planned to evaluate the efficacy and safety (short- and long-term) of “Nourishing Baby Oil” in infants, between 1 to 12 months of age.

### **Study design**

This was a prospective, open, phase III clinical trial, conducted at the “Well Baby Clinic” of the Department of Pediatrics, Medical College and Hospital, Kolkata from September to December 2004, as per the GCP guidelines.

### **Inclusion and exclusion criteria**

Babies between the age of 1 to 12 months, born at term with a birth weight of more than 2500g, having appropriate gain in weight, length and head circumference and a normal psychomotor development, and whose parents were willing to give informed written consent were included in the study. Babies suffering from some systemic or topical disease, babies who were under some medication, and those babies whose parents are unwilling to give informed written consent were excluded from the study.

### **Study procedure**

The parents who brought their infants for routine check up at the “Well Baby Clinic” were informed about the study products, their effects, duration of study period, their responsibilities, the importance of compliance, ethical aspects, and overall plan of the study. Informed consent was obtained in writing from parents of all included infants.

At the initial visit, a detailed medical history was obtained by interviewing the parents regarding any dermatological problem encountered in the infant so far, or any adverse effect following the use of any baby product on the infant. Then, a detailed physical examination of the infant was done including the dermatological examination.

Initially, the baby oil was applied to the back of the elbow in a small quantity, and was kept for 30 minutes. The applied area was observed for any kind of immediate hypersensitivity reaction, and if there was no immediate reaction, the mode of application of the “Nourishing Baby Oil” was explained to the parents. All the parents were advised to apply a small amount of “Nourishing Baby Oil” (Batch No. 40701 – RD) using firm but gentle strokes all over the baby, which was followed by gentle massage.

The signs and symptoms of immediate skin irritation and delayed hypersensitivity reactions were evaluated as per the standard guidelines. The scoring scale for evaluating erythema was predefined on a score scale of 0 to 4, as; No erythema=0, Very slight erythema=1, Well defined erythema=2, Moderate to severe erythema=3, and Very severe erythema=4. The scoring scale for evaluating edema was predefined on a score scale of 0 to 4 as: No edema=0, Very slight edema=1, Slight edema=2, Moderate edema=3, and Severe edema=4. The scoring scale for evaluating pruritus and urticaria was predefined on a score scale of 0 to 4 as: No pruritus and urticaria=0, Very slight pruritus and urticaria=1, Well defined pruritus and urticaria=2, Moderate to severe pruritus and urticaria=3, and Severe pruritus and urticaria=4.

### **Follow-up and monitoring**

The parents were instructed to visit the “Well Baby Clinic” with their infants on the 7<sup>th</sup> and 14<sup>th</sup> day of application. At each follow-up visit a detailed history and clinical examination was done for evaluating the therapeutic efficacy and any adverse effect seen during the period. They were asked to discontinue the product usage, if they noticed any adverse effect. In case any adverse reaction was recorded, the product was discontinued till the adverse reaction disappeared, and then the product was reintroduced for the same duration to observe recurrence of the previous reaction.

### **Adverse events**

All the adverse events either reported or observed by the parents were recorded with information about onset, severity, duration and site of the adverse reaction. The relation of adverse events to the study product was predefined as “Unrelated”, “Probable” and “Possible”.

### **Results**

A total of 30 babies were included in the study, and all the included babies completed the study. In 15 (50%) babies, there was a significant reduction in skin dryness, after one application, and after a week’s period, there was total improvement in the skin dryness in all the included babies. After the application of “Nourishing Baby Oil”, in 23 (77%) babies, there was excellent improvement and in 7 (23%) babies there was good improvement in the skin feel, which became softer. In 25 (83%) babies, there was excellent improvement and in 5 (17%) babies, there was good improvement in the overall skin glow. All the parents were comfortable with the appearance, fragrance, and the overall characteristics of the formulation.

There were no immediate or delayed type of hypersensitivity reaction (erythema, edema, pruritus or urticaria), either observed by investigators or reported by the parents. There were no dropouts, and the overall compliance to the “Nourishing Baby Oil” was excellent.

### **Discussion**

There is a growing realization that the stratum corneum, while providing a barrier to water loss, is a unique, intricate biosensor. Stratum corneum responds to environmental challenges and surface trauma by initiating a series of biologic processes, which rapidly restore barrier homeostasis.<sup>1</sup> The barrier function of the stratum corneum is a fundamental element in maintaining cutaneous hydration. Alteration in the stratum corneum leads to the loss of this barrier function, with increased transdermal water loss, decreased water content and xerosis. 60% of newborns exhibit physiologic desquamation, demonstrating a transitory functional deficit in the stratum corneum. In the premature babies, the epidermis and particularly the stratum corneum are immature; trans-epidermal water loss is elevated and the skin is dry or

even fissural. Cutaneous hydration improves the aspect of the skin and also decreases the number of infectious episodes.<sup>2</sup>

Xerosis is characterized by rough or coarse skin. There are structural modifications in the stratum corneum, with abnormalities in keratinization, and proliferation. Treatment is essentially local, and is accompanied by general measures like application of oils, moisturizers, etc. A variety of skin diseases, which are characterized by itch sensation tend to worsen during the dry winter season. One study suggests that a low environmental humidity increases mast cell number and dermal histamine content.<sup>3</sup>

As documented in various studies, baby massage aids growth and development, enhances the bond between the mother and the child, and helps premature babies gain weight. This study observed significant reduction in the skin dryness, improvement in the softness of the skin, and skin glow. It was also noticed that, the “Nourishing Baby Oil” was absorbed rapidly, leaving the baby’s skin soft with a natural, healthy glow and without any greasy after-feel. These beneficial effects might have been due to the synergistic actions (skin nourishing, emollient, moisturizing, soothing, antimicrobial, anti-inflammatory, and antioxidant) of its ingredients, which have been well documented.

Various studies have documented the anti-inflammatory and analgesic activity of *Sida cordifolia*.<sup>4,5</sup> Auddy et al., demonstrated the antioxidant activity of *Sida cordifolia*.<sup>6</sup> The active ingredients of *Olea europaea* are flavonoids apigenin, apigenin-O-rhamnosylglucoside, apigenin-O-glucoside, luteolin, luteolin-O-glucoside, luteolin-O-glucoside, chrysoeriol, chrysoeriol-glucoside, quercetin-O-rhamnoside,<sup>7</sup> aldehydes (E-2-hexenal), terpenoids (E-alpha-farnesene, linalool, beta-caryophyllene, and valencene).<sup>8</sup> The oil of *Olea europaea* has antioxidant<sup>9</sup> and antimicrobial<sup>10</sup> properties.

The active principles in *Withania somnifera* are withaferin A, withanosides,<sup>11</sup> coumarins, scopoletin aesculetin, triterpene, and phytosterols. Kaur et al., demonstrated the antioxidant and antiproliferative activity of *Withania somnifera*.<sup>12</sup> Various studies have demonstrated the anticancer activity of *Withania somnifera* in skin carcinomas induced by UV B radiation.<sup>13</sup> Arora et al., demonstrated the antibacterial efficacy of *Withania somnifera*.<sup>14</sup> Davis et al., observed the inhibition of delayed type hypersensitivity reaction by *Withania somnifera*.<sup>15</sup> Scartezzini et al., demonstrated the antioxidant activity of *Withania somnifera*.<sup>16</sup>

*Vetiveria zizanioides* is a potent emollients and act as moisturizing, soothing agent. The principle ingredients of *Vetiveria zizanioides* are valencene, octadecenamide, hexamethyl - tetracosahexaene, benzendicarboxylic acid, di-isooctyl ester, and terpenoids (monoterpenes, sequiterpenes and triterpene).<sup>17</sup>

The principle constituents of *Aloe barbadensis* are anthraquinones (aloe-emodin and aloin A / barbalin),<sup>18</sup> cinnamoyl, p-coumaroyl, feruloyl, caffeoyl aloesin, aloemannan,<sup>19</sup> acemannan, verectin,<sup>20</sup> elgonica dimer A and bisbenzopyran.<sup>19</sup> *Aloe vera* has been evaluated for its anti-inflammatory activity by various researchers. Hegggers *et al.* demonstrated that the extracts of *Aloe vera* gel have anti-inflammatory activity and suggested its inhibitory action on the arachidonic acid pathway via cyclo-oxygenase.<sup>21</sup> Davis *et al.* demonstrated that *Aloe vera* blocks the suppression of wound-healing by hydrocortisone acetate. *Aloe vera* masks the effects of wound-healing inhibitors such as sterols and certain amino acids.<sup>22,23</sup> When applied topically, *Aloe vera* plays an important role in the wound-healing process. Choi et al., isolated and characterized a glycoprotein fraction (G1G1M1DI2) from *Aloe vera*, which was

demonstrated effective in wound healing, and the proposed action was via cell proliferation and migration. This effect of G1G1M1DI2 on cell migration was confirmed on a monolayer of human keratinocytes and when this fraction was tested on a raft culture, it stimulated the formation of epidermal tissue. Furthermore, proliferation markers (epidermal growth factor receptor, fibronectin receptor, fibronectin, keratin 5/14 and keratin 1/10) were markedly expressed at the immunohistochemical level.<sup>24</sup> Chithra et al., studied the influence of *Aloe vera* on the glycosaminoglycan components of the matrix in a healing wound and observed increased levels of the glycohydrolases on treatment with *Aloe vera*, indicating increased turnover of the matrix. Both topical and oral treatments with *Aloe vera* were found to have a positive influence on the synthesis of glycosaminoglycans and thereby were found to be beneficial in wound healing.<sup>25,26</sup> *Aloe vera* contains a basic peroxidase, when applied topically and scavenges H<sub>2</sub>O<sub>2</sub> in skin surface.<sup>27,28</sup> Hegggers et al., observed that *Aloe vera* expedites wound contraction and neutralizes the wound-retardant effect due to increased collagen activity, which is enhanced by a lectin, which consequently improves collagen matrix and enhances breaking strength.<sup>21</sup>

## Conclusion

Infantile dry skin (xerosis) is a common skin condition, which is associated with a defect in skin barrier function. Oil massaging benefits infants in many ways such as aiding growth and development, and building intimacy and bonding between the mother and the child. Massaging with oil also helps in maintaining the skin moisture equilibrium. The “Nourishing Baby Oil” is a polyherbal formulation recommended for the prevention and management of infantile dry skin. This study was planned to evaluate the efficacy and safety (short- and long-term) of “Nourishing Baby Oil” in infants, between 1 to 12 months of age.

This study observed a significant reduction in skin dryness, improvement in the softness of the skin, and skin glow. It was also noticed that the “Nourishing Baby Oil” was absorbed rapidly, leaving the baby skin soft with a natural, healthy glow and without any greasy after-feel. These beneficial effects might have been due to the synergistic actions (skin nourishing, emollient, moisturizing, soothing, antimicrobial, antiinflammatory, and antioxidant) of its ingredients.

Therefore, it may be concluded that the “Nourishing Baby Oil” is effective and safe in infantile xerosis.

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