

# Evaluation of the efficacy and safety of “Baby Powder” in infantile hyperhidrosis, miliaria rubra and bad body odor

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## ABSTRACT

*Infantile hyperhidrosis and miliaria rubra are the commonly encountered dermal problems, which are often associated with bad body odor. The “Baby Powder” is a polyherbal formulation recommended for prevention and treatment of infantile hyperhidrosis, miliaria rubra, and bad body odor, and this study was conducted to evaluate the efficacy and safety of “Baby Powder” in infantile hyperhidrosis, miliaria rubra, and bad body odor.*

*The study was a prospective clinical trial, conducted as per the good clinical practice guidelines. A total of 20 infants, who were suffering from hyperhidrosis, miliaria rubra, and bad body odor, and whose parents were willing to give informed written consent were included in the study. Infants who were under some medication for systemic or topical disease, and those babies, whose parents were unwilling to give written informed consent, were excluded from the study. At the initial visit, a detailed medical history was obtained by interviewing the parents regarding any dermatological problems, or any adverse effect following the use of any baby product in the infant. Then a detailed physical examination of the infant was done including the dermatological system. The parents were instructed to apply the “Baby Powder” once daily, after bath for a period of 2 weeks, all over the body. 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, and at each follow-up visit a detailed clinical examination was done. All the adverse events either reported or observed by the parents were recorded with the information about onset, severity, duration and site of the adverse reaction. The signs and symptoms of immediate skin irritation and delayed hypersensitivity reactions were evaluated as per the standard reference guidelines.*

*This study observed significant improvement in hyperhidrosis, miliaria rubra, and bad body odor, in 3 days of time, and complete recovery after a week’s application. Also, there were no clinically significant adverse reactions during the entire study period. These results might have been due to the synergistic activities of the ingredients of the Baby Powder. Therefore, it may be concluded that the “Baby Powder” is clinically effective and safe in the management of infantile hyperhidrosis, miliaria rubra, and bad body odor.*

## INTRODUCTION

A baby's skin is extremely sensitive, delicate, and vulnerable to various dermal disorders.<sup>1</sup> Infantile hyperhidrosis and miliaria rubra (prickly heat) are the commonly encountered dermal problems, which are often associated with bad body odor. Hyperhidrosis is characterized by excessive sweating as a result from localized hyperstimulation of sweat glands by cholinergic sympathetic nerve fibers.<sup>2,3</sup> Miliaria rubra is an acute inflammatory pruritic eruption due to the blockage of sweat gland ducts and the retained sweat. The bad body odor is a result of interactions between the commensal microorganisms, dermal humidity, and environmental pollutants.<sup>4,5</sup>

The “Baby Powder” is a polyherbal formulation recommended for the prevention and treatment of infantile hyperhidrosis, miliaria rubra, and bad body odor, and it contains the oils of *Santalum album*, *Vetiveria zizanoides* and *Olea europaea*, and the powder of *Yashada bhasma*. This study was conducted to evaluate the efficacy and safety of “Baby Powder” in infantile hyperhidrosis, miliaria rubra, and bad body odor.

### **Aim of the study**

This study was planned to evaluate the clinical efficacy and safety (short- and long-term) of “Baby Powder” in the management of infantile hyperhidrosis, miliaria rubra, and bad body odor.

### **Study design**

The study was a prospective clinical trial, conducted at the Well Baby Clinic, at the Department of Pediatrics, Medical College and Hospital, Kolkata, from September to December 2004, as per the good clinical practice guidelines.

## **METHODS AND MATERIALS**

### **Inclusion and exclusion criteria**

A total of 20 infants of age 1-12 months, who were suffering from hyperhidrosis, miliaria rubra, and bad body odor; who were born at term with a birth weight of more than 2500 grams (having appropriate gain in weight, length, and head circumference, and a normal psychomotor development on pediatric physical examination), and whose parents were willing to give informed written consent were included in the study. Infants who were under some medication for systemic or topical disease, and those babies, whose parents were unwilling to give written informed consent before entering the study, 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 product, its 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 the parents of all included infants.

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

Before beginning the study, the “Baby Powder”(Batch No.: FD/BP/03) was applied in a test dose for immediate application, and any adverse effect was recorded after half hour. If there was no such immediate adverse effect, the parents were instructed to apply the “Baby Powder” once daily, after bath for a period of 2 weeks, all over the body.

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 for reporting. They were asked to discontinue the product, if they noticed any adverse effect. All the infants were followed up on the 7<sup>th</sup> and 14<sup>th</sup> day of application, and at each follow up visit a detailed clinical examination was done.

## **Adverse events**

All the adverse events either reported or observed by the parents were recorded with information about the onset, severity, duration and site of the adverse reaction. The signs and symptoms of immediate skin irritation and delayed hypersensitivity reactions were evaluated as per the standard reference guidelines. The scoring scales for various adverse effects were as follows: Scoring scale for evaluating erythema: No erythema – 0, Very slight erythema – 1, Well defined erythema – 2, Moderate to severe erythema – 3, and Very severe erythema – 4. Scoring scale for evaluating edema: No edema – 0, Very slight edema – 1, Slight edema – 2, Moderate edema – 3, and Severe edema – 4. Scoring scale for evaluating pruritus and urticaria: Nil 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.<sup>6</sup>

The relation of adverse events to the study product was predefined as “*Unrelated*” (a reaction that does not follow a reasonable temporal sequence from the time of application of the product and not localized to the whole site of application), “*Probable*” (follows a known responsible pattern to the suspected product, but could have been produced by the baby’s clinical state and localized at the site of application), “*possible*” (follows a known responsible pattern to the suspected product that could not be reasonably explained by the known characteristics of the baby’s clinical state and localized at the site of application).

## **RESULTS**

There was a significant improvement in hyperhidrosis, miliaria rubra, and bad body odor, in all the included babies, in 3 days of time, and there was complete recovery from the concerned conditions, after a week’s application, in all the included babies.

There were no clinically significant adverse reactions (either reported by the parents or observed by the investigators) during the entire study period. There were no dropouts, and the overall compliance to the product use was excellent.

## **DISCUSSION**

Hyperhidrosis is the excessive perspiration due to over-activity of the sweat glands. Hyperhidrosis may be a contributory factor in various skin diseases (fungal or pyogenic infections and contact dermatitis), and generalized hyperhidrosis frequently accompanies fever. Localized hyperhidrosis usually occurs in otherwise healthy persons, and is confined to the palms, soles, axillae, inframammary regions, or groin. In hyperhidrosis, the skin in affected areas is often pink or bluish white, and in severe cases, the skin may be macerated, and fissured.

Local treatment with medicated dusting powder is the treatment of choice. Due to the refined particle size, the dusting powders absorb the excess moisture, which causes drying of the excessive sweat.<sup>4</sup>

Miliaria usually occurs in warm humid weather, in which the horny layer of the epidermis swells, and obstructs the eccrine sweat gland ducts. Sweat fails to reach the skin surface and is trapped in the epidermis or dermis, where it causes irritation (prickling) and severe itching. Appearance of the lesions depends on the depth of the obstruction. In miliaria crystallina, ductal obstruction is in the uppermost epidermis, and the typical minute lesions are tense transparent vesicles without inflammation. In miliaria rubra, obstruction with inflammation occurs deeper in the epidermal acrosyringium, and the lesions are red. In miliaria profunda,

ductal obstruction occurs at the entrance of the duct into the dermal papillae; it is the deepest and most severe form of miliaria. Miliaria profunda manifests with larger, deeper-seated, frequently painful papules. Intertriginous areas are favored. Treatment is symptomatic (cooling and drying the involved areas) and prophylactic (avoiding conditions that may induce sweating), and the medicated dusting powders is the treatment of choice.<sup>5</sup>

This study observed a significant improvement in the hyperhidrosis, miliaria rubra, and bad body odor, in 3 days of time, and a complete recovery after a week's application. Also, there were no clinically significant adverse reactions during the entire study period. These results might have been due to the synergistic activities of the ingredients of the Baby Powder, which have been well documented.

The main constituents of *Santalum album* oil are santalolol, furfurol, and santalene. Sandalwood oil relieves itching and inflammation of the skin, and is very useful in the management of scarring, dry eczema, and dehydrated skin. The oil of *Santalum album* has potent antioxidant,<sup>7</sup> and antimicrobial activities.<sup>8</sup> Oil of *Santalum album* is also effective against various dermal disorders.<sup>9</sup>

The principle ingredients of *Vetiveria zizanioides* are valencene, octadecenamide-hexamethyl-tetracosahexaene-benzendicarboxylic acid, di-isooctyl ester, and terpenoids (monoterpenes, sesquiterpenes and triterpene).<sup>10</sup> *Vetiveria zizanioides* is a potent emollient and acts as a moisturizing and soothing agent.

The active ingredients of *Olea europaea* are flavonoids apigenin, apigenin-hamnosylglucoside, apigenin-glucoside, luteolin, luteolin-glucoside, chrysoeriol, chrysoeriol-glucoside and quercetin-rhamnoside,<sup>11</sup> aldehydes (E-2-hexenal), terpenoids (E-alpha-farnesene, linalool, beta-caryophyllene, and valencene),<sup>12,13</sup> and tyrosol.<sup>12,14</sup> The oil of *Olea europaea* has antioxidant properties<sup>15</sup> and antimicrobial activity.<sup>16</sup>

Yashada bhasma is specially prepared by processing in zinc, which plays a significant role in wound healing. Zinc has been shown to be beneficial in various dermal disorders, due to its astringent and antimicrobial properties. In one experimental study, Zinc was found to be efficacious in preventing epidermal atrophy, and dermal degeneration (edema, collagen fiber loss, and hair follicle atrophy).<sup>17</sup>

## CONCLUSION

Infantile hyperhidrosis and miliaria rubra are the commonly encountered dermal problems, which are often associated with bad body odor. The "Baby Powder" is a polyherbal formulation recommended for the prevention and treatment of infantile hyperhidrosis, miliaria rubra, and bad body odor, and this study was conducted to evaluate the efficacy and safety of "Baby Powder" in infantile hyperhidrosis, miliaria rubra, and bad body odor.

This study observed a significant improvement in the hyperhidrosis, miliaria rubra, and bad body odor, in 3 days of time, and a complete recovery after a week's application. Also, there were no clinically significant adverse reactions during the entire study period. These results might have been due to the synergistic activities of the ingredients of the "Baby Powder".

Therefore, it may be concluded that the "Baby Powder" is clinically effective and safe in the management of infantile hyperhidrosis, miliaria rubra, and bad body odor.

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