

Comparison of Rice Starch Powder and Zinc Oxide Cream for the Prevention of Irritant Diaper Dermatitis

Nadda Samakayanusorn MD*, Suthida Chaithirayanon MD**, Thep Chalermchai MD*,
Suwirakorn Ophaswongs MD*, Nampen Siriwat MD*, Montree Udompataikul MD*

* Skin Center, Faculty of Medicine, Srinakharinwirot University, Bangkok, Thailand

** Department of Pediatrics, Faculty of Medicine, Srinakharinwirot University, Nakhon Nayok, Thailand

Background: Diaper dermatitis is a common skin disorder during infancy. A recent study indicated that efficacy in preventing diaper dermatitis using talcum powder was five times less than zinc oxide cream, and research demonstrated that talcum powder usage was associated with lung diseases and ovarian cancer in adults. Due to these limitations, rice starch powder, an organic substance with water repellent, may be benefit in preventing diaper dermatitis. As there has been no study of the effectiveness of rice starch powder, it was investigated in the present study.

Objective: To compare the effectiveness of rice starch powder with zinc oxide cream for the prevention of diaper dermatitis

Material and Method: A total of 104 healthy infants, aged between 6 and 24 months with normal skin in the diaper area were divided equally into two groups. One group was applied with rice starch powder over the diaper area and the other with zinc oxide cream. Both groups used the same disposable diapers with four supplied per day. Clinical outcomes were evaluated at the 4th and 8th week for the occurrence and duration of the disease, with clinical severity assessed using the diaper dermatitis severity scoring scale. Parental satisfaction was also evaluated and side effects were recorded.

Results: One hundred infants, 56 males and 44 females completed the study with average age 12.6 months. The diaper dermatitis occurrence in the rice starch powder group was 26 percent (n = 13) whereas it was 22 percent (n = 11) in the zinc oxide cream group. This showed no statistically significant difference between two groups (p = 0.584). Median time to event for infants applied with rice starch powder was 22 days (IQR: 21 to 23) and 26 days for the zinc oxide cream group (IQR: 20 to 31) with no statistically significant difference (p = 0.105, log rank test). Multivariate analysis using the Cox proportional hazard regression model found that the risk of diaper dermatitis occurrence in the rice starch powder group was 3.5 times higher than in the zinc oxide cream group (95% CI: 0.7 to 16.1), with no statistically significant difference (p = 0.105). No adverse effects resulted from the use of the test substances in either group.

Conclusion: Rice starch powder can be considered as an alternative choice for preventing diaper dermatitis.

Keywords: Diaper dermatitis, Rice starch powder, Talcum powder, Zinc oxide cream

J Med Assoc Thai 2017; 100 (Suppl. 8): S1-S6

Full text. e-Journal: <http://www.jmatonline.com>

Diaper dermatitis is one of the most common skin disorders in infants⁽¹⁾, caused by prolonged contact with urine and feces⁽²⁾. Occlusion increases skin hydration and raises skin pH, while exposure to fecal enzymes damages the integrity of the skin barrier. The skin susceptible to irritants and microbial invasion, leading to localized skin inflammation^(3,4). The best management for diaper dermatitis is prevention. Topical zinc oxide cream is an effective barrier cream with re-epithelialization and anti-inflammatory properties, used

as a standard regimen for both treatment and prevention of diaper dermatitis⁽⁵⁻⁷⁾. In Thailand, baby powder consisting of talc (magnesium trisilicate) is favored to prevent diaper rash because it has a drying effect and causes less friction on the skin⁽⁸⁾. Moreover, talcum powder is cheap and available at local stores. However, its use has been associated with an increase in lung diseases⁽⁹⁾ and ovarian cancer in adults^(10,11). In addition, previous studies suggested that the efficacy of talcum powder was 5.3 times less than zinc oxide cream for the prevention of diaper dermatitis⁽¹²⁾. Thus, risks involved in using talcum powder are high.

Rice has always been the main Thai exported goods. One of the innovative, derivative products is rice starch powder. It is a modified starch obtained from rice which has chemical composition of aluminum starch

Correspondence to:

Chaithirayanon S, Department of Pediatrics, Faculty of Medicine, Srinakharinwirot University, 63 Ongkharak, Nakhon Nayok 26120, Thailand.

Phone: +66-37-395085

E-mail: learnla117@hotmail.com

octenylsuccinate⁽¹³⁾. It has water repelled properties (hydrophobicity), can decrease friction and is a biodegradable substance⁽¹⁴⁾. It is proved to be safe when used in a cosmetic formula, neither being a sensitizer nor an irritant⁽¹⁵⁾. Regarding its properties, together with finding an alternative product instead of talcum powder, the effectiveness of rice starch powder for preventing diaper dermatitis was investigated in the present study.

Material and Method

This experimental, investigator-blinded, prospective randomized controlled trial was carried out at the Department of Pediatrics, Faculty of Medicine, Srinakharinwirot University, and approved by the Clinical Ethics Committee of Human Study, Srinakharinwirot University (SWUEC/F-298/2559).

The healthy Thai infants, aged between 6 to 24 months old were enrolled. Written informed consents were obtained from all of their parents. The infants must have normal skin at the diaper areas at the beginning of the study. They must refrain from the use of systemic corticosteroid within 12 weeks and topical corticosteroids or calcineurin inhibitors within 8 weeks prior to the study. The infants who had skin disorders or other systemic diseases or the history of allergy to either powder composition made from rice or cream containing zinc oxide, were excluded from the study.

The sample size was calculated at 96 infants using 'PS: Power and Sample Size' a program by Dupont WD and Plummer WD⁽¹⁶⁾, according to the previous study of Siriluck et al in 2014⁽¹²⁾. To allow for a 10% drop out, 104 infants were enrolled. The infants were equally randomized using the blocked randomization method and blinded to the study investigator. The infants were given either rice starch powder or zinc oxide cream applied over the diaper area before their diaper were changed every time. In the rice starch powder group, an amount of half a teaspoon (equal to about 1 gram) was applied and in the zinc oxide group, an amount of approximately two finger joints (equal to about 1 gram) was applied. The study investigator collected the patients' basic information and recorded the information about the care of skin under the diaper area, which was used as the fundamental value. Photographs of the diaper area were taken. Both groups were controlled using the same disposable diapers with four supplied per day. Parents were educated regarding diaper area care and instructed to record changes in their infants' skin daily throughout the study period. If diaper dermatitis occurred, a doctor's appointment was

scheduled for clinical evaluation and severity of the disease was graded by diaper rash and erythema scoring scale⁽¹⁷⁾. Then, the doctor would provide treatment of the disease. There were two appointments scheduled in the 4th week and 8th week. The infants were examined as follows: physical examination and checking for diaper rash were conducted by the researching physician. Then, the patients' information was collected from the parents along with completion of the questionnaire asking about the quantities of usage, other types of care of the skin areas under the diaper, score of parental satisfaction (range from 0 to 5, the 5 score was representative of the most satisfaction) and adverse reactions in order to assess the parents' satisfaction regarding the use of the test substances.

Results were followed-up at the 4th and the 8th week to evaluate the occurrence of diaper dermatitis, time-to-event outcome, duration of the disease, severity of the disease, risk factors affecting diaper dermatitis occurrence, parents' satisfaction and side effects. The median time to event outcome was analyzed using survival analysis and the log rank test. Risk factors of the disease (hazard ratio) evaluated at the 8th week were analyzed using univariate and multivariate analysis based on Cox's proportional hazard model. Severity of the disease was graded by diaper rash and erythema scoring scale, while comparison between the rice starch powder group and the zinc oxide cream group was evaluated by the Chi-square test. Descriptive analysis was used to assess parental satisfaction with rice starch powder and zinc oxide cream and adverse reaction during the study was also recorded. The *p*-value of less than 0.05 was considered as a statistically significant difference.

Results

A total of one hundred infants completed the study. Four infants (two from each group) left during the study due to protocol withdrawal (loss to follow-up). Fifty-six males (56%) and forty-four females (44%) were analyzed; average age was 12.6 months. Demographic information including weight, height, underlying disease, nutrition status, drug allergy and vaccination history did not differ between the two groups (Table 1). Furthermore, no significant differences in the baseline characteristics of parented care of the diaper area and history of diaper dermatitis were recorded between the two groups (Table 2).

The diaper dermatitis occurrence in the rice starch powder group was 26 percent (*n* = 13) whereas it was 22 percent (*n* = 11) in the zinc oxide cream group.

Table 1. Baseline demographics

Demographic data	Rice starch powder group (n = 50)	Zinc oxide group (n = 50)	p-value
Age (mean ± SD; months)	13.2±5.7	12.1±5.5	0.327
Weight (mean ± SD; kg)	9.5±1.9	9.4±1.9	0.692
Height (mean ± SD; cm)	73.5±8.9	72.6±11.1	0.669
Gender			
Male (%)	27 (48.2)	29 (51.8)	
Female (%)	23 (52.3)	21 (47.7)	0.687
Full vaccination history			
Yes (%)	50 (50.0)	50 (50.0)	
No (%)	0 (0.0)	0 (0.0)	1.000

Table 2. Comparison of history of diaper dermatitis and baseline characteristics of parented care at the diaper area

	Rice starch powder group (n = 50)	Zinc oxide group (n = 50)	p-value
History of diaper dermatitis			
Yes (%)	22 (48.9)	23 (51.1)	0.650
No (%)	28 (50.9)	27 (49.1)	
Type of diapers used			
Cloth diapers (%)	1 (25.0)	3 (75.0)	0.434
Disposable diapers (%)	49 (51.0)	47 (49.0)	
Use of bathing products			
Water (%)	0 (0.0)	1 (100.0)	0.513
Soap (%)	2 (66.7)	1 (33.3)	
Liquid soap (%)	48 (50.0)	48 (50.0)	
Times of changing diaper per day (mean ± SD)	4.0±1.7	3.7±2.0	0.299

This showed no statistically significant difference between two groups ($p = 0.584$). The median time to event was 22 days (IQR: 21 to 23) for the rice starch powder group and 26 days (IQR: 20 to 31) for the zinc oxide cream group, with no statistically significant differences ($p = 0.105$, log rank test) (Fig. 1). Diaper dermatitis duration (mean ± SD) of the rice powder group was 5.6±3.2 days while that of the zinc oxide cream group was 2.4±1.3 days with statistically significant difference ($p = 0.033$). The severity of diaper dermatitis for both groups was at mild and moderate levels with no statistically significant differences ($p = 0.460$) (Table 3).

Multivariate analysis using the Cox proportional hazard model to assess the risk of diaper dermatitis occurrence between the two groups determined that within the controls of factors affecting diaper dermatitis occurrence and the independent factors, the rice starch powder group had 3.5 times

(95% CI: 0.7 to 16.1) greater risk of diaper dermatitis occurrence; however, there was no statistically significant difference between the two groups ($p = 0.105$).

Average score of parental satisfaction was 4.5±0.8 for the rice starch powder group and 4.6±0.6 for the zinc oxide cream group with no statistically significant difference ($p = 0.317$) (Fig. 2). No adverse effects from the use of the test substances were recorded.

Discussion

Prevention of diaper dermatitis consists of the avoidance of aggravating factors using absorbent disposable diapers which are changed frequently and proper care are important. The topical barrier cream application is also beneficial in preventing diaper rash. Zinc oxide cream is a highly effective barrier. Research has demonstrated the effectiveness of zinc oxide cream

Table 3. Diaper dermatitis outcome data

Diaper dermatitis outcome	Rice starch powder group (n = 50)	Zinc oxide group (n = 50)	p-value
Diaper dermatitis occurrence			
Yes (%)	13 (54.2)	11 (45.8)	0.584
No (%)	37 (48.7)	39 (51.3)	
Severity of diaper dermatitis			
Slight (%)	8 (61.5)	5 (38.5)	0.460
Mild (%)	2 (28.6)	5 (71.4)	
Mild to moderate (%)	1 (50.0)	1 (50.0)	
Moderate (%)	2 (100.0)	0 (0.0)	
Moderate to severe (%)	0 (0.0)	0 (0.0)	
Severe (%)	0 (0.0)	0 (0.0)	
Diaper dermatitis duration (days) (mean ± SD)	5.6±3.2	2.4±1.3	0.033

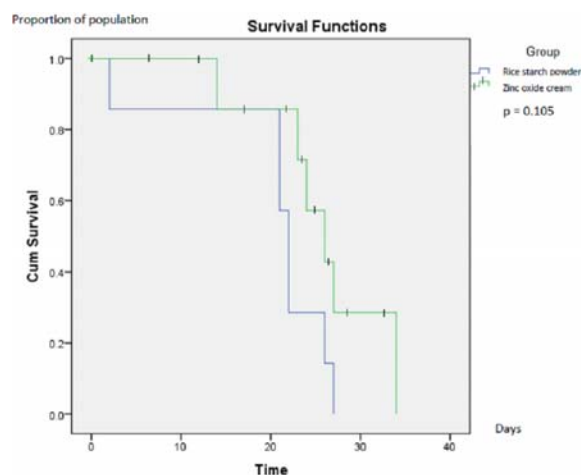


Fig. 1 Comparison of the median time to event between the rice starch powder and zinc oxide group ($p = 0.317$).

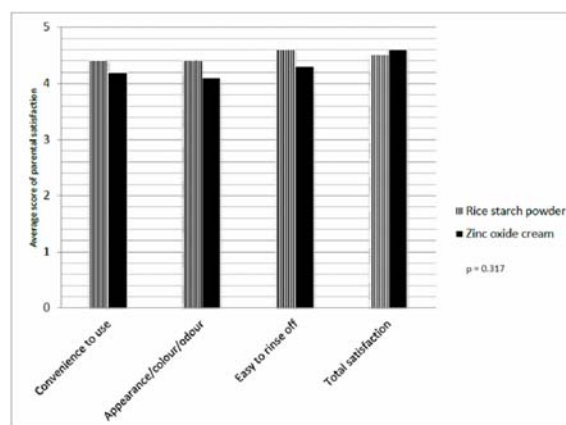


Fig. 2 Parental satisfaction between the rice starch powder and zinc oxide group.

for preventing diaper dermatitis^(5,7). Baldwin et al⁽⁷⁾ determined that a zinc oxide group had less severity of disease than a control group at the end of the 4th experimental week. Nevertheless, they are difficulties in washing off; aggressive cleansing was needed of the skin when removing, which caused irritation.

Baby powder or talcum powder is popular for preventing diaper dermatitis in many countries including Thailand, although there may be side effects from massive inhalation of talcum powder and risk of ovarian cancer in adults⁽⁹⁻¹¹⁾. Siriluck et al⁽¹²⁾ indicated that talcum powder could prevent diaper dermatitis; nevertheless, it had a higher incidence of disease, shorter median time to event and 5.3 times higher risk of diaper dermatitis occurrence than zinc

oxide cream. It was the empirical evidence of disadvantages of talcum powder comparing to the zinc oxide cream.

Thailand grows rice and processes it into rice starch powder, which causes dry skin due to its water repelled properties⁽¹⁴⁾ while also reducing skin friction. These properties of rice starch powder and the intention to reduce adverse reactions from talcum powder contact culminated in the concept of the present study. The rice starch powder and zinc oxide cream groups recorded the same incidence of diaper dermatitis occurrence with no statistically significant differences and also the median time to event and severity of disease. However, the rice starch powder group had longer disease duration than the zinc oxide cream group with statistically significant difference. This was because

zinc has the property of wound healing and anti-inflammation, which was not found in rice starch powder. Factors which might affect diaper dermatitis occurrence in the present study were types of test substance applied to the diaper area (rice starch powder: zinc oxide cream), frequency of changing diaper per day (less than 4 times: more than or 4 times), duration of wearing diaper (number of hour more than or 8 hours: less than 8 hours) and diaper dermatitis history (yes: no). It was found that within the controls of the independent factors, the rice powder group had 3.5 times (0.7 to 16.1) greater risk of diaper dermatitis occurrence; however, there was no significant difference between the two groups. No adverse reactions were recorded from the use of rice starch powder.

Results in the present study showed other evidence to support zinc oxide cream effectiveness. Moreover, rice starch powder could prevent diaper dermatitis similarly to zinc oxide cream. In conclusion, rice starch powder can be considered as an alternative choice for preventing diaper dermatitis.

Limitations of this study included the lack of objective measurements such as the erythema index using a mexameter. These measurements should be included in further studies. In addition, the issues of random error of population may also affect the study results.

What is already known on this topic?

Talcum powder used for preventing diaper dermatitis recorded a higher incidence of disease, shorter median time to event, and 5.3 times higher risk of diaper dermatitis occurrence than zinc oxide and petrolatum cream.

What this study adds?

Additional information that rice starch powder could prevent diaper dermatitis with the same efficiency as zinc oxide cream, but with no effect on the duration of disease was presented. Thus, rice starch powder is an alternative substance for preventing diaper dermatitis.

Acknowledgements

We are grateful to the Faculty of Medicine, Srinakharinwirot University for a supporting grant for this study.

Potential conflicts of interest

None.

References

1. Klunk C, Domingues E, Wiss K. An update on diaper dermatitis. *Clin Dermatol* 2014; 32: 477-87.
2. Berg RW. Etiology and pathophysiology of diaper dermatitis. *Adv Dermatol* 1988; 3: 75-98.
3. Atherton DJ. A review of the pathophysiology, prevention and treatment of irritant diaper dermatitis. *Curr Med Res Opin* 2004; 20: 645-9.
4. Shin HT. Diagnosis and management of diaper dermatitis. *Pediatr Clin North Am* 2014; 61: 367-82.
5. Visscher MO. Update on the use of topical agents in neonates. *Newborn Infant Nurs Rev* 2009; 9: 31-47.
6. Moore J. Can zinc oxide have an impact on wound healing? *Pediatric Today* 2003; 16: 22-5.
7. Baldwin S, Odio MR, Haines SL, O'Connor RJ, Englehart JS, Lane AT. Skin benefits from continuous topical administration of a zinc oxide/petrolatum formulation by a novel disposable diaper. *J Eur Acad Dermatol Venereol* 2001; (15 Suppl 1): 5-11.
8. Mierczynska-Vasilev A, Ralston J, Beattie DA. Absorption of modified dextrans on talc: effect of surface coverage and hydration water on hydrophobicity reduction. *Langmuir* 2008; 24: 6121-7.
9. Oberdorster G. The NTP talc inhalation study: a critical appraisal focused on lung particle overload. *Regul Toxicol Pharmacol* 1995; 21: 233-41.
10. Huncharek M, Geschwind JF, Kupelnick B. Perineal application of cosmetic talc and risk of invasive epithelial ovarian cancer: a meta-analysis of 11,933 subjects from sixteen observational studies. *Anticancer Res* 2003; 23: 1955-60.
11. Houghton SC, Reeves KW, Hankinson SE, Crawford L, Lane D, Wactawski-Wende J, et al. Perineal powder use and risk of ovarian cancer. *J Natl Cancer Inst* 2014; 106. pii: dju208.
12. Chaithirayanon S, Aroonchit S, Chalermchai T, Treesirichod A, Udompataikul M. Comparative study between talcum and zinc oxide cream for the prevention of irritant contact diaper dermatitis in infants. *J Med Assoc Thai* 2016; 99 (Suppl 8): S1-6.
13. Wenninger JA, Mcewan GN. International cosmetic ingredient dictionary and handbook. 7th ed. Washington DC: CTFA; 1997.
14. Sweedman MC, Tizzotti MJ, Schafer C, Gilbert RG. Structure and physicochemical properties of octenyl succinic anhydride modified starches: a review. *Carbohydr Polym* 2013; 92: 905-20.
15. Nair B, Yamarik TA. Final report on the safety

- assessment of aluminum starch octenylsuccinate. *Int J Toxicol* 2002; 21 (Suppl 1): 1-7.
16. Dupont WD, Plummer WD Jr. Power and sample size calculations for studies involving linear regression. *Control Clin Trials* 1998; 19: 589-601.
17. Odio MR, O'Connor RJ, Sarbaugh F, Baldwin S. Continuous topical administration of a petrolatum formulation by a novel disposable diaper. 2. Effect on skin condition. *Dermatology* 2000; 200: 238-43.

การศึกษาเปรียบเทียบประสิทธิผลของแป้งที่ทำจากข้าวเทียบกับการใช้ซิงค์ออกไซด์ครีมในการป้องกันการเกิดโรคผื่นผ้าอ้อม

ณัฏดา สามัคยานุสรณ์, สุธิดา ชัยธีระยานนท์, เทพ เฉลิมชัย, สุวีรากร โอภาสวงศ์, น้ำเพ็ญ ศิริวัฒน์, มนตรี อุดมเพทายกุล

ภูมิหลัง: โรคผื่นผ้าอ้อมเป็นโรคผิวหนังที่พบได้บ่อยในช่วงเด็กทารกการรักษาคือการป้องกัน จากงานวิจัยที่ผ่านมาพบว่าแป้งทัลคัมมีประสิทธิภาพดีกว่าเมื่อเทียบกับซิงค์ออกไซด์ครีมในการป้องกันโรคผื่นผ้าอ้อม อีกทั้งตัวแป้งทัลคัมเองยังมีรายงานการก่อให้เกิดภาวะปอดอักเสบในเด็กที่ใช้ และยังมีการศึกษาถึงความเกี่ยวข้องระหว่างแป้งทัลคัมกับการเกิดมะเร็งรังไข่ในผู้ใหญ่ ในปัจจุบันจึงมีการนำแป้งที่แปรรูปจากข้าวเจ้าซึ่งเป็นสารอินทรีย์ที่มีคุณสมบัติในการไล่น้ำเพื่อช่วยลดความอับชื้นนำมาใช้ในผลิตภัณฑ์เครื่องสำอางซึ่งน่าจะมีประโยชน์ในการป้องกันผื่นผ้าอ้อม และเป็นการลดความเสี่ยงของการเกิดผลข้างเคียงจากการสัมผัสแป้งทัลคัม ทั้งนี้เนื่องจากยังไม่เคยมีการศึกษาถึงประสิทธิผลของแป้งที่ทำจากข้าวในด้านการป้องกันโรคผื่นผ้าอ้อมมาก่อน จึงนำมาสู่แนวคิดในการศึกษาวิจัยนี้

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบประสิทธิผลของแป้งที่ทำจากข้าวเทียบกับการใช้ซิงค์ออกไซด์ครีมในการป้องกัน อุบัติการณ์การเกิดโรคผื่นผ้าอ้อม **วัสดุและวิธีการ:** ผู้เข้าร่วมวิจัยเป็นอาสาสมัครเด็กเพศชายหรือหญิงอายุ 6 เดือน 2 ปีมีสุขภาพดีและมีสภาพผิวบริเวณ ใต้ผ้าอ้อมเป็นปกติจำนวนทั้งสิ้น 104 คน แบ่งผู้เข้าร่วมวิจัยเป็น 2 กลุ่มกลุ่มละ 52 คน ได้แก่ กลุ่มที่ได้รับ สารป้องกันการเกิดผื่นผ้าอ้อมเป็นแป้งที่ทำจากข้าวหรือซิงค์ออกไซด์ครีม โดยทาให้ครอบคลุมบริเวณใต้ผ้าอ้อมทั้งหมดทุกครั้งที่มีการเปลี่ยนผ้าอ้อมและติดตามผลในสัปดาห์ที่ 4 และ 8 เพื่อประเมินผลในด้านอุบัติการณ์การเกิดผื่นผ้าอ้อม ระยะเวลาที่เกิดโรคตั้งแต่เริ่มได้รับสารทดลอง จำนวนอาสาสมัครที่เกิดผื่นผ้าอ้อม ในระหว่างงานวิจัยความรุนแรงของผื่นผ้าอ้อมที่เกิดขึ้นในแต่ละกลุ่มตามแบบประเมิน Diaper rash and erythema scoring scale อาการไม่พึงประสงค์ที่เกิดขึ้นในระหว่างการวิจัยและความพึงพอใจของผู้ปกครองต่อสารทดสอบ

ผลการศึกษา: อาสาสมัครทั้งสิ้น 100 คนเป็นเพศชาย 56 คน (ร้อยละ 56) เพศหญิง 44 คน (ร้อยละ 44) อายุเฉลี่ย 12.6 เดือน ผลการศึกษาเปรียบเทียบอุบัติการณ์การเกิดผื่นผ้าอ้อมพบว่า กลุ่มที่ได้รับแป้งที่ทำจากข้าว มีอาสาสมัครที่เกิดโรค 13 คน (ร้อยละ 26) และกลุ่มที่ได้รับซิงค์ออกไซด์ครีม 11 คน (ร้อยละ 22) ซึ่งทั้งสองกลุ่มไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.584$) ระยะเวลาค่าเฉลี่ยตั้งแต่เริ่มต้นการวิจัยจนเกิดโรค (median time to event) กลุ่มทดลองที่ได้รับแป้งที่ทำจากข้าวมีระยะเวลาเท่ากับ 22 วัน (IQR: 21 ถึง 23) และกลุ่มควบคุมที่ได้รับซิงค์ออกไซด์ครีมมีระยะเวลาเท่ากับ 26 วัน (IQR: 20 ถึง 31) ซึ่งไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.105$, Log rank test) วิเคราะห์แบบหลายตัวแปรด้วยวิธี Cox proportional hazard model หาค่าความเสี่ยงการเกิดผื่นผ้าอ้อมเปรียบเทียบระหว่างสองกลุ่ม โดยกลุ่มที่ได้รับแป้งที่ทำจากข้าวมีความเสี่ยงในการเกิดโรคมากกว่า 3.5 เท่า (95% CI: 0.7 ถึง 16.1) แต่อย่างไรก็ตามพบว่าไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p = 0.105$) ไม่พบว่า มีผลข้างเคียงต่อสารทดสอบและความพึงพอใจต่อสารทดสอบอยู่ระดับดีถึงดีมากทั้งสองกลุ่มโดยไม่มี ความแตกต่างกันระหว่างสองกลุ่ม

สรุป: แป้งที่ทำจากข้าวสามารถใช้เป็นตัวเลือกในการป้องกันการเกิดผื่นผ้าอ้อมในทารกได้