

Prevalence and cumulative incidence of eczema in infants fed goat or cow milk based formula

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Why we did this study

- Eczema can be extremely distressing in babies and parents, affecting quality of life through chronic sleep disturbance. However, few studies have been published examining the incidence of eczema in the first 12 months of life.
- A double blind, controlled feeding trial in Australia followed healthy term infants from 2 weeks to 12 months of age. The formula-fed infants were randomly allocated to exclusively use goat milk or cow milk formula for 4 months, while a reference group of exclusively breastfed infants was also included.
- As part of the clinical trial, a trained nurse assessed the babies at 1,2,3,4,6 and 12 months of age for eczema severity, using SCORing Atopic Dermatitis (SCORAD) in all children with visible eczema.

What we learned from *post-hoc* analysis of this clinical study

- The greatest incidence of eczema was observed in infants at 6 months age (11.7% of the 285 infants assessed). The prevalence was 9.6% at 4 months age and 7.9% at 12 months age.
- Over the 12 months, 14% of the infants receiving goat milk infant formula showed signs of eczema. This is a 40% reduction compared with the 23% of the infants fed cow milk infant formula. In the breast-fed group, 21% of the infants showed signs of eczema at some time during the first 12 months.
- Twice as many infants fed the cow infant formula experienced a non-trivial rash (ie SCORAD > 10) compared to the infants fed the goat milk infant formula, ie 16% vs 7%, respectively.
- The trend for a reduced incidence of eczema in the goat milk formula group was not affected by family history of allergy.

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Abstract

Objectives and study: Eczema is an intermittent non-infective inflammatory skin disease inflicting between 15 and 20% of children in developed countries. Eczema can be extremely distressing in babies and parents, affecting quality of life through chronic sleep disturbance. It often leads to exclusion of certain foods on the basis that they are thought to exacerbate the symptoms of eczema. The objectives of this study were to (i) describe the prevalence and cumulative incidence of eczema in a group of unselected infants in Australia followed prospectively from within 2 weeks of birth to the age of 12 months and (ii) to evaluate the association with type of feeding in first 4 months.

Methods: This was a post-hoc analysis of data from a multi-centre, double blind, controlled feeding trial in Australia (Australia and New Zealand Clinical Trials Registry ACTRN12608000047392). Healthy term infants were randomly allocated to goat milk or cow milk formula before they were 2 weeks of age (Br J Nutr. 2014;111:1641). The goat milk infant formula (goat IF) was manufactured by Dairy Goat Co-operative (NZ) Ltd using whole goat milk without added whey proteins, with a blend of milk fat and vegetable oils. The control cow infant formula (cow IF) contained skimmed cow milk and whey proteins, with vegetable oils as the sole source of fat. Infants were fed study formula to at least 4 months of age, with no other liquids or solids. A reference group of exclusively breastfed infants was included. A study nurse, trained to diagnose visible symptoms of eczema, assessed the babies at 1,2,3,4,6 and 12 months of age. Eczema severity was also assessed using SCORing Atopic Dermatitis (SCORAD) in all children with visible eczema.

Results: A total of 285 infants had eczema assessments; 94, 91 and 100 in the goat IF, cow IF and breast-fed groups, respectively. The prevalence of infants with any symptoms of eczema were 1.8%, 3.9%, 9.6%, 11.7% and 7.9% at 2,3,4,6 and 12 months. The cumulative incidence of eczema over the 12 months was 14%, 23% and 21% in the goat IF, cow IF and breast-fed groups, respectively. The incidence of eczema with SCORAD above 10 (to exclude those with trivial rash only) were 7%, 16% and 14% in the goat IF, cow IF and breast-fed groups, respectively. A family history of atopy (mother, father and /or siblings) was found in 73% of subjects.

Table: The association between types of feeding in first 4 months and eczema expressed as odds ratio with 95% confidence interval (CI) and after adjusting for family history of allergy were

Group comparison	Adjusted Odds Ratio (95% CI)	Adjusted p value
Cow IF/Goat IF	2.04 (0.92, 4.52)	0.08
Cow IF/breastfed	1.21 (0.60, 2.45)	0.59
Goat IF/breastfed	0.59 (0.27, 1.29)	0.19

Conclusion: This study is important in providing evidence regarding the prevalence and cumulative incidence of skin complaints such as eczema in infants in the first 12 months of life after fed formula made from goat milk or cow milk. The prevalence of eczema appears to peak at 4-6 months of age. By 12 months fewer infants exhibited any symptoms of eczema. While the number of infants with eczema was insufficient to accurately determine the relative risk of eczema of goat milk compared to cow milk, these data suggest there is a trend for a lower incidence in the goat whole milk formula group, compared to the cow formula group. This observation should be tested in a larger, adequately powered randomised controlled trial.

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Background

Eczema / atopic dermatitis (AD) is a common inflammatory skin disease; worldwide epidemiological surveys report incidences of over 15% in many developed countries. Eczema can be extremely distressing for babies and their parents, affecting quality of life through chronic sleep disturbance. However, few longitudinal studies have reported the incidence of eczema in healthy term infants below 12 months of age.

The study

This was a post-hoc analysis of data from a multi-centre, double blind, controlled feeding trial in Australia (ANZ Clinical Trials Registry ACTRN12608000047392)¹. In this study we (i) describe the prevalence and cumulative incidence of eczema in a group of unselected infants followed from 2 weeks of birth to the age of 12 months and (ii) evaluate the association of eczema with type of infant feeding in the first 4 months.

Enrolment within 2 weeks of birth

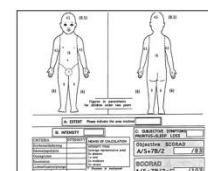
- 200 infants who were already exclusively infant formula feeding*
- 100 infants of mothers who planned to exclusively breastfeed for at least 4 months

- * Infants randomised to receive:
 - Goat whole milk IF (GIF) or
 - Cow milk IF (CIF)



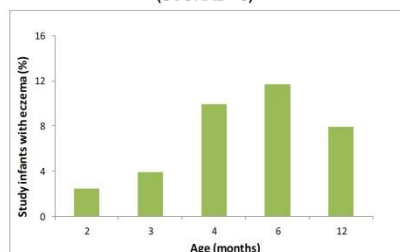
Each infant was assessed for eczema by a trained study nurse at 6 time points through the 12 month study (↑). Visible symptoms of eczema were assessed using SCORing Atopic Dermatitis (SCORAD).

	Goat Whole Milk Infant Formula (/100 kcal)	Cow Infant Formula (/100 kcal)
Energy	65.6 kcal/100 ml	64.8 kcal/100 ml
Protein (g)	2.0	2.1
Whey Casein	20.80	60.40
Fat (g)	5.3	5.2
Fat source	60% milk fat + 40% vegetable oils	Vegetable oils



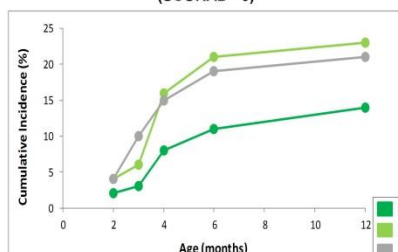
Results

Prevalence of infants with symptoms of eczema (SCORAD > 0)



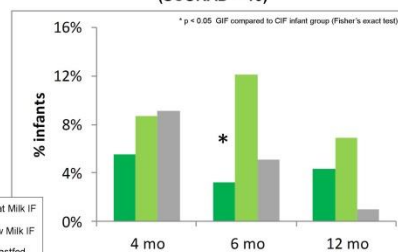
- Visible symptoms of eczema were observed in some infants within 2 months of age
- The incidence of eczema was maximal at the 4 and 6 month time points
- 12% of the study infants showed visible eczema signs, which was less than expected from previous reports²

Cumulative incidence of eczema (SCORAD > 0)



- Compared to the other two groups, the cumulative incidence of eczema (SCORAD > 0) in the 12 month study was reduced in the Goat Milk Infant Formula group, although this was not statistically significant.

Incidence of non-trivial eczema (SCORAD > 10)



- The incidence of eczema with SCORAD > 10 (to exclude those infants with trivial rash) was reduced in the Goat Milk formula group, compared to the Cow Milk formula group. This was statistically significant at 6 months age.

Family History?

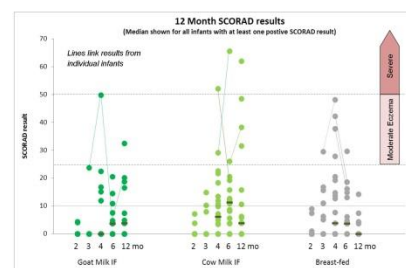
Study infants were not pre-selected on family history of allergies. However, this information was gathered at recruitment. Odds ratios for a positive eczema outcome (SCORAD > 0) were calculated for the comparison groups shown, after adjusting to test whether the effect of feeding group was modified by a family history of allergy. Results indicate the trend for reduced incidence of eczema in the goat whole milk formula group remained.

Group comparison	Adjusted Odds Ratio (95% CI)	Adjusted p value
Cow IF/Goat IF	2.04 (0.92, 4.52)	0.08
Cow IF/breastfed	1.21 (0.60, 2.45)	0.59
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Conclusion

This study provides evidence of the prevalence and cumulative incidence of skin complaints, such as eczema, in infants in their first 12 months of life, after exclusive feeding of infant formula made from whole goat milk or whey-adjusted cow milk. The prevalence of eczema appears to peak at 4-6 months of age, with fewer infants exhibiting any eczema symptoms by 12 months.

The number of infants with eczema was insufficient to accurately determine the relative risk of eczema for infants consuming whole goat milk formula compared to cow milk formula. However, the data suggest there is a trend for a lower incidence of eczema in the whole goat milk formula group. This observation warrants further testing in a larger, adequately powered randomised controlled trial.



1. Zhou SJ, Sullivan T, et al. Nutritional adequacy of goat milk infant formulas for term infants: a double-blind randomised controlled trial. *Br J Nutr* 2014; 1-11.

2. Snijders BE, Thijs C, et al. Breastfeeding and infant eczema in the first year of life in the KOALA birth cohort study: a risk period-specific analysis. *Pediatrics* 2007; 119(1): e137-41.

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