Technical Review

Dairy Goat Co-operative (N.Z.) Ltd

Russian clinical trials comparing allergy to goat and cow milk in infants and young children

Denisova SN, Vakhrameeva SN, Ivanina EK, Konno VI (2003) Formula 'Nanny' in diet therapy of atopic dermatitis in infants. Voprosy Detskoi Dermatolgii 1: 86-89

Denisova SN, Sentsova TB, Belitskaya M Yu, Korotkova TN, Balabolkin II, Yukhtina NV, Vakhrameeva SN (2004) Voprosy Detskoi Dermatolgii 3: 42-46

Background

The aim of the two clinical studies was to assess the effectiveness of goat milk formulae to reduce the symptoms of atopic dermatitis in infants and young children who were allergic to cow milk proteins. The goat milk formulae (infant and growing up) were manufactured by Dairy Goat Co-operative (N.Z.) Ltd (DGC). The studies were conducted in Russia and published in Russian medical journals. English translations were made by The Translation Service, Wellington, New Zealand. The key points from the two trials are summarised below.

Trial 1 (Denisova et al, 2003)

- 67[1] infants aged 1-9 months, exhibiting symptoms of allergy to cow milk were enrolled in the study
- Main symptoms were atopic dermatitis
- Allergy to cow milk was also confirmed by measuring serum IgE antibodies to cow milk proteins
- The goat milk infant formula was introduced gradually, replacing previously used formula over 10-14 days
- They were then fed goat milk infant formula for another 3-12 months

Results

- Goat milk reduced the atopic dermatitis symptoms in 59 of the 67 infants (88%)
- 18 children had previously tried a soy formula and another 12 were given hydrolysate formula. Neither of these formulae were effective in reducing the symptoms of allergy, whereas the goat milk formula was
- Symptoms started to improve 1-3 weeks after introducing goat milk formula
- All 8 infants who did not respond to goat milk, had allergy symptoms for more than 5 months before being given the goat milk formula. These children had also developed reactions to other foods, not just milk.

Trial 2 (Denisova et al, 2004)

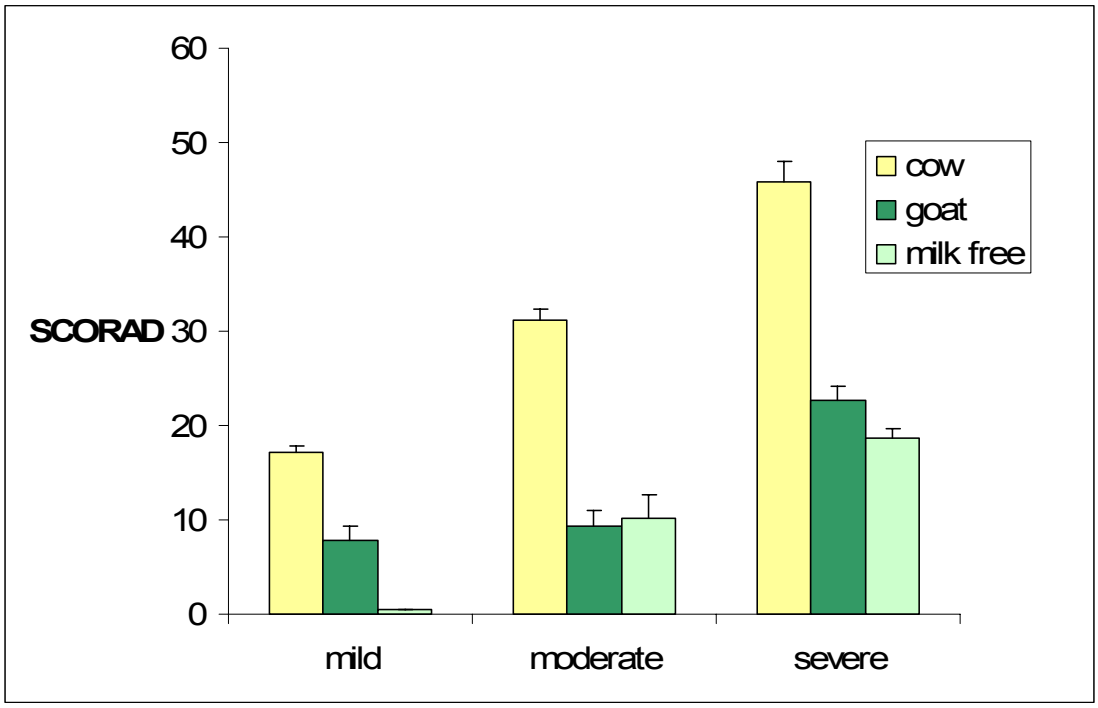
- 41 children (12-36 months old) exhibiting symptoms of allergy to cow milk were enrolled in the study
- Main symptoms were atopic dermatitis

[1] The summary of the published paper says there were fifty infants in the trial. This appears to be a mistake. In the main part of the published paper it states that there were 67 infants, consisting of 32 boys aged between 1 and 9 months and 35 girls aged between 2.5 and 9 months.

- Allergy to cow milk was also confirmed by measuring serum IgE antibodies to cow milk proteins
- The goat milk infant formula was introduced gradually, replacing previously used formula over 10-14 days
- They were then fed goat milk infant formula for another 3-12 months
- Severity of dermatitis was assessed by SCORAD. The higher the SCORAD value, the more extensive the dermatitis was.

Results

- Goat milk reduced the symptoms of allergy in 33 of 41 children (80%)
- Not all symptoms were relieved. Dryness of skin persisted, whilst the itching, dampness and red rash disappeared.
- The response depended on initial severity of the atopic dermatitis. In the group with severe dermatitis (SCORAD >40), goat milk reduced the symptoms to levels similar to mild dermatitis (SCORAD <20) – see figure.
- The symptoms remaining after the change to goat milk formula was equivalent to patients on a milk-free diet.
- Symptoms only started to improve 1-3 weeks after introducing the goat milk formula. IgE antibodies to milk proteins did not return to normal levels until after 1.5 – 2 months on goat milk.
- 38 children did not show a benefit when given soy or hydrolysate formulae, but did respond well to the goat milk formula.



The degree of atopic dermatitis in 41 young children (12-36 months old) before and after the switch from cow to goat growing-up milk formula. The goat formula reduced dermatitis in children with moderate and severe dermatitis]
as if milk was completely removed from the diet (milk free).

Summary

The key conclusion from these studies was that goat milk formula was effective in reducing symptoms of atopic dermatitis in at least 80-88% of infants and young children who had already developed an allergy to cow milk proteins. The reduction in symptoms was not immediate, taking at least 1-3 weeks for a significant reduction in atopic dermatitis and 1.5 to 2 months for IgE antibodies to milk proteins to decline to normal.

Goat milk was less effective where treatment of infants less than 12 months was delayed for 5 months or more (Denisova et al, 2003). This delay allows time for allergies to develop to other food proteins and for the severity of atopic dermatitis to increase. In the second trial, atopic dermatitis was not completely eliminated after introduction of goat growing up milk formula to children aged 1-3 years, but the reduction in symptoms was equivalent to patients on a milk-free diet (Denisova et al, 2004). This also indicates that other non-milk factors are causing atopic dermatitis and is consistent with the finding in younger infants that delaying treatment reduces the effectiveness of this treatment (Denisova et al, 2003). Thus early introduction of goat milk formula is indicated to minimize risk of escalation of allergy.

It is significant that in both trials, goat milk formula was also able to relieve allergy symptoms in infants where milk hydrolysates or soy milk had previously been of no benefit.

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Colin Prosser

Chief Scientific Officer

Dairy Goat Co-operative (N.Z.) Ltd

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Formula 'Nanny' in Diet Therapy of Atopic Dermatitis in Infants

S. N. Denisova*, S. N. Vakhrameeva**, E. K. Ivanina*** and V. I. Konno***

* G. N. Speranskii Children's Municipal Clinical Hospital No. 9, Moscow
** Children's Health Scientific Research Centre, Russian Academy of Medical Sciences, Moscow
*** Moscow Scientific Research Institute for Paediatrics and Paediatric Surgery,
Ministry of Health, Russian Federation

Fifty 1-9 month old babies diagnosed with sub-acute common-form atopic dermatitis, were monitored for 3-12 months under outpatient conditions. It was established that skin inflammation symptoms started to improve 1-3 weeks after the beginning of treatment in 88% of all the babies monitored. The total level of blood serum IgE increased 5 to 20 folds: up to 48.3 ± 7.2 IU/ml (13-55 IU/ml) in twenty two out of the 32 babies subjected to immunological examination in comparison with the control group, which included only apparently healthy babies (1.8-6.6 IU/ml). The same babies showed an increased level of specific IgE-antibodies to cow's milk protein. In the remaining ten children, the total IgE level was at the same level as that of the control group children. The trials of 'Nanny' use in diet therapy showed that a remission was achieved in the majority of infants allergic to cows milk proteins.
Key words: atopic dermatitis, food allergy, immunoglobulin E.

Food allergy, the earliest allergic reaction in babies, is triggered off by certain foods. Cow's milk allergy accounts for the most common allergic reaction in under-one-year-olds (70-80% of all allergies).

Atopic dermatitis (AD) is a form of allergic reaction to milk. According to different authors [1-4], it is encountered in 10-20% of all the children of the age group studied. The factors believed to cause allergy to cow's milk proteinare: antenatal sensitisation, feeding a newborn with a formula while still in maternity hospital, transfer of baby to combined or bottle feeding with a formula based on cow's milk and postnatal sensitisation. As cow's and soymilk proteins are important allergy-causing agents, responsible for dermatitis in infants, diet therapy (along with treatment applied to the affected areas) is the most important treatment of this disorder. Selecting physiologically wholesome formulas, free of cow's milk proteins, is the most important diet treatment of atopic dermatitis [4, 5].

The use of a wide range of specialist products recommended for treatment or prevention is not always effective in AD treatment. This emphasises the importance of using new approaches to finding substitutes for products based on cow's milk, which would eliminate AD while ensuring adequate growth and development in children.

Table 1. Protein Content in Whole Cow's and Goat's Milk, g per litre

	Cow's milk	Goat's milk
Caseins:		
α-casein	13.7 (1s- α)	-
β-casein	6.2	22.8
γ-casein	1.2	-
χ-casein	3.7	-
Serum protein:		
β-lactoglobulin	3.0	2.6
α-lactalbumin	0.7	4.3
Immunoglobulin	0.6	-
Serum albumin	0.3	-
Total:	29.4	29.7

In the last decades, Western scientists carried out scientific research aimed at evaluating the effectiveness of goat's milk in babies' diet. They established that babies' tolerance to goat's milk and their growth and weight gain were not inferior to those in babies fed cow's milk [6]. Similar results were obtained in the studies where human milk substitutes based on goat's milk were compared with those based on cow's milk [7].

Most informative data were obtained when the use of goat's milk and human milk substitutes based on goat's milk were tried on babies with intolerance and/or allergy to cow's milk protein. British scientists [8] established over many years of studies that only 1 out of 100 children with cow's milk allergy was also allergic to goat's milk. It was demonstrated that the use of goat's milk in the diet of 300 children with bronchial asthma, the main cause of which was allergy to cow's milk protein, remission was achieved in 270 children [5, 9, 10]. The positive effect of goat's milk in babies with a food allergy was attributed to the physico-chemical structure of goat's milk, which is quite different from that of cow's milk (Table 1).

In comparison with cow's milk, goat's milk lacks α1s-casein or γ-casein. Its main casein component is β-casein. The main serum protein of goat's milk is β -lactalbumin, while that of cow's milk is α -lactoglobulin (Table 1).

It needs to be emphasised that goat's milk proteins are not only compositionally different from cow's milk proteins. They are structurally different.

In this respect, the data concerned with feeding AD babies on a human milk substitute based on goat's milk, the antigenic structure of which is different from that of cow's milk proteins, was of special interest [4].

The present authors carried out a two-year course of clinical studies of the effectiveness of the new goat's-milk-based 'Nanny' formula on under-one-year-olds with AD. The studies were longitudinal, retrospective/prospective, and complied with the 'Feed Clinical Practice' requirements.

The program included 67 outpatient children (32 boys aged between 1 and 9 months and 35 girls aged between 2.5 and 9 months) diagnosed with common AD (sub-acute form). The children were fed with the formula studied for 3-12 months.

The symptoms of atopical dermatitis in all the children coincided with their transfer from breastfeeding to combined or bottle feeding with adapted cow's milk formulas. Transferring 18 of these children to a soy-based formula and 12 others to a formula based on cow's milk protein hydrolysates proved ineffective. Six of the children studied had hereditary anamnesis complicated by atopy.

The severity of AD was measured on the SCORAD scale [11], taking into consideration the spreading and intensity of skin symptoms, subjective symptoms (such as disturbed sleep and itching) and the total size of the affected area. The responsiveness of AD symptoms to the application of 'Nanny' was the criterion of its effectiveness.

Total blood serum IgE was measured, using the quantitative immunoferment method. Specific IgE-antibodies to particular food allergens were identified, using the solid-phase two-stage immune-ferment analysis (reagents manufactured by the 'DIA Plus' Company).

'Nanny' was introduced into the children's diet gradually, replacing all the previously used formulas after 10-14 days. Depending the child's age, the total daily intake of 'Nanny' varied between 500 and 700 ml. The children were fed this formula for 3-12 months. The diet therapy, which included substituting 'Nanny' for the formulas used previously and adjusting the children's food supplements, was combined with application of ointment in all the children, taking into consideration their skin irritation level. In some of the children, antihistamine preparations were used simultaneously with 'Nanny' diet therapy.

The chemical composition of 'Nanny' as compared to human milk and Russian requirements to the chemical composition of human milk substitutes is shown in Table 2.

Table 2. Chemical composition of 'Nanny' (per 1 l of liquid)

Composition	Goat's milk	Cow's milk	'Nanny'	Mature human milk	Human milk substitute composition recommended in Russia
Proteins, g	29-31	28-33	15.5	11.5	15-18
Fats, g	41	40	38.0	42.0	38
Carbohydrates, g	43	46	73.0	71	70
Minerals, mg					
Na	360	390	280	170	250
K	2,280	1,500	610	510	600
Ca	1,020	1,140	650	340	500-600
P	880	870	340	140	300
Mg	118	93	49	30	50-60
Fe	0.7	0.3	8.3	0.5	10-12
Zn	4.1	3.7	4.8	3.3	2.5-3
Vitamins					
A, µg	2.5	0.8	710	610	700-800
D, µg	0.6	0.3	10	-	10
E, µg	0.6	1.0	16	2.4	5
K, µg	-	-	62	-	25-30
C, mg	11	14	98	52	60

The protein content of 'Nanny' (1.5 g/100 ml) is lower than that of goat's milk, while its carbohydrate content is higher, due to the introduction lactose. The casein/albumin ratio in 'Nanny' is 8:2 because it is based on dry whole goat's milk, which has not been enriched with extra milk serum. 'Nanny's mineral and vitamin contents are also close to those of human milk. Thus, 'Nanny' contains 0.85mg/100 ml Fe, which meets the present standards (5-7 mg/1 l for earliest formulas and 10-12 mg/l for further formulas). Osmolarity of reduced 'Nanny' equals 316 mOsm/kg, which is similar to human milk osmolarity: 280 mOsm/kg.

The patients were subdivided into 3 groups in accordance with their SCORAD index.

The mild form of the illness was diagnosed in 19 patients (their SCORAD index was 18.9 ± 0.26). Skin symptoms, consisting of moderate erythema, dryness and isolated papules, were restricted to the face and extremities. A medium-acute form of the illness was observed in 22 children (SCORAD index 33.1 ± 2.0). Skin inflammation was characterised by erythema, swelling, lichenification, considerable dryness, peeling and itch.

Acute AD was diagnosed in 26 children (SCORAD index 60.6 ± 4.8). Pathological changes covered large areas of the skin and were of more serious nature: considerable erythema and swelling, numerous papules, suppuration, scabs, escoriation and lichenification. Itching and disturbed sleep were also observed.

The total IgE level of blood serum was considerably higher than normal (more than 5-20 fold) in forty children out of the 52 on whom immunological examination was carried out. It was reliably increased up to 48.3 ± 7.2 ME/ml (13-155 ME/ml) in comparison with the control group (1.8 - 6.6 ME/ml). For the same children a high level of IgE antibodies to cow's milk proteins was characteristic. In 12 other children, the general IgE level was no different from that in the control group children.

AD acuteness did not depend on the general IgE level or on the presence of specific IgE antibodies to cow's milk proteins. This group of patients included children with mild, medium-severe and severe forms of skin symptoms.

These observations showed that tolerance to 'Nanny' was good in most children. Their growth was adequate. The average monthly weight gain was 704 ± 81.1 g.

In most patients (44 out of 50), skin conditions started to improve after 1-3 weeks of treatment. Hyperemia, itch, rash, flaking and suppuration disappeared in virtually all the children. Dryness of skin persisted in some children.

However, the introduction of 'Nanny' had no effect on AD in 8 out of 67 children. Five out of the 40 children suffering from allergy to cow's milk proteins and 3 out of the 12 children with normal IgE had no positive response to 'Nanny'.

We analysed every individual case when a positive response to 'Nanny' was lacking and established that late referral to the doctor was common to all of them, the illness was left untreated for more than 5 months, and the children contained not only IgE-antibodies to food proteins but also antibodies to other everyday communal allergens. Moreover, some of these children were given

whole goat's milk. Later on, these children were transferred to a no-milk diet. Overall results showed that the administering of 'Nanny' resulted in AD remission in most children (88%).

It should be emphasised that diet therapy, which included 'Nanny', had a beneficial effect on the children who had not benefited from specialist baby foods based on soy protein isolates and protein hydrolysates.

Most children with specific IgE-antibodies to cow's milk protein showed considerable improvement in their skin symptoms as a result of diet therapy, which included 'Nanny'.

Diet therapy with the inclusion of 'Nanny' showed that the use of 'Nanny' resulted in an AD remission in most children.

The new results have confirmed our previous studies. We believe that these results are sufficiently convincing in proving that it is worthwhile to include the new category of human milk substitutes, based on goat's milk among specialist baby foods for the diet therapy of intolerance to cow's milk proteins and for preventing food allergy in very young children.

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Using a Fortified Formula Based on Goat's Milk in the Treatment of Atopic Dermatitis in Young Children

S. M. Denisova[1], T. B. Sentsova[2], M. Yu. Belitskaya[1], T. N. Korotkova[2], I. I. Balabolkin[2], N. V. Yukhtina[2] and S. N.Vakhrameeva[2]

[1] G. N. Speransky Children's Municipal Clinical Hospital No. 9, Moscow

[2] Scientific Center for Children's Health, Russian Academy of Medical Sciences, Moscow

This article aims at investigating the effect of the adapted goat's-milk-based 'Gold Nanny-Goat' formula on patients suffering from atopic dermatitis caused by their allergy to cow's milk protein. The test group included 41 children with atypical dermatitis. The control group included 38 children on a milk-free diet. The average age of the children in both groups was 18 months. The study showed that 33 out of 41 children on the diet based on goat's milk went into remission. The same happened to most of the control group children. Immunological data showed a clear trend in IgE and Ig of cow's milk and soy milk protein antibodies towards normalisation in all the children. The results suggest that introduction of a formula based on goat's milk into the diet of children suffering from atopic dermatitis assists their diet therapy.

Key words: children, atopical dermatitis, diet therapy, goat's milk

Food allergy in little children, including breast-fed children, has been on the rise recently [1, 2]. Allergies can be manifested in different ways: regurgitation, vomiting, atopic, acute gastroentheritis, hemorrhagic diarrhea, edema, rash, bronchial asthma [3, 4].

As has been shown in our previous studies, human milk substitutes based on goat's milk were effective in treatment of atopic dermatitis in under-one-year olds [5, 9]. However, atopic dermatitis often occurs in older children. During the first three years of life, it is often triggered by transferring a child from breastfeeding or from feeding with an adapted formula to whole cow's milk. Prescribing 'Golden Nanny-Goat', a formula based on goat's milk (Vitacare, New Zealand) or 'Amalea' (CBM, Holland), fortified whole goat's milk, is beneficial.

However, no clinical assessment of the effectiveness of the above products has so far been carried out in Russia.

Having this in mind, we aimed at studying the effect 'Golden Nanny-Goat' has on atopic dermatitis in young children suffering from an allergy to cow's milk proteins.

PATIENTS AND METHODS

The total number of children studied on an outpatient basis was 41 (28 boys and 13 girls), their age ranging from 12 to 36 months. All the children in this (the main) group suffered from atopic dermatitis. The control group included 38 children (20 boys and 18 girls) of the same age group who were on a milk-free diet. The latter group included children who were prescribed previously either therapeutic products based on hydrolysates of cow's milk proteins, soy-milk isolates or formulas based on goat's milk, but these have not been effective. The average age of the children studied was 18 months. The study continued for 3 to 12 months.

Atopic dermatitis in the children studied started when they were transferred from breast feeding to adapted formulas based on cow's milk or to whole cow's milk or when supplementary food was introduced. Eight control group children, in addition to suffering from skin allergy symptoms, had a high carbohydrate content in their faeces. Allergy was hereditary in 11 main group and 13 control group children.

The positive effect of the new diet was measured by the effect it had on clinical and immunological symptoms of atopic dermatitis.

The SCORAD index was applied for clinical assessment of the severity of atopic dermatitis [10]. The following immunological study methods were used: measuring General IgE in blood serum, measuring allergen-specific IgG and IgE to cow's milk proteins, β-lactoglobulin, casein and soy protein. General IgE of blood serum was measured with an immuno-chemical 'Access' analyser (Beckman Couter, USA), using monospecific reagents. Allergen-specific IgG and IgE antibodies to cow's milk proteins, β-lactoglobulin, casein and soy protein were measured, using 'Coda', an immuno-ferment analyser (Bio Rad, USA) and commercial 'Allergopharma' sets (Germany). The symptom that prompted immunological examination was severe or continuously recurring atopic dermatitis, the fact that one could not use other diagnostic methods, such as taking skin probes by scarring or pricking, provocative allergy agent tests, orprovocative diet. Immunological examination was implemented only after a

voluntary parental permission was given (the parents had the benefit of a thorough explanation).

Diet therapy for atopic dermatitis (including cow's milk and cow dairy products or replacing them with 'Golden Nanny-Goat' and adjusting supplementary feeding) was combined with the application of external medical preparations, depending on how severe the skin inflammation was. For some children, antihistamine preparations were also used. The product tested was introduced into the diet gradually, completely replacing the previously used formulas or cow's milk in 10-14 days. A child was administered 300-500 ml a day, depending on the child's weight.

'Golden Nanny-Goat' is a vitamin enriched formula. This specialist product is designed for over one year olds. It contains whole goat's milk, lactose, vegetable oils (sunflower and canola), dry goat's milk cream, taurine, choline chloride, minerals and vitamins (see Table 1). The formula was made from ecologically clean goat's milk in New Zealand. All supplementary components were obtained from natural products of vegetative origin. Their genetic structure has not been modified. 'Golden Nanny-Goat' is permitted in Russia for 1-3 years olds (Sanitary/Epidemiological Decision No. 77.99.02.916.D004253.06.03, dated 20 June 2003).

Table 1. Composition of Fortified Milk Formula 'Gold Nanny-Goat'

Composition		Per 100 ml of ready to use formula	Per 100 g dry powder
Proteins	g	2.2	16.3
Carbohydrates	g	6.6	50.0
Fats	g	3.5	26.5
Linoleic acid (ω–6)	mg	0.53	4.0
α–linoleic acid (ω-3)	mg	66	500
Minerals:			
Calcium	mg	105	780
Phosphorus	mg	65	490
Sodium	mg	27	200
Potassium	mg	110	830
Chloride	mg	95	715
Magnesium	mg	8.5	64
Iron	mg	0.9	6.8
Zink	mg	0.49	3.7
Iodine	µg	9.3	70
Manganese	µg	8.0	60
Copper	µg	49	370
Vitamins			
Vitamin A	µg	73	550
Vitamin D	µg	1.0	7.8
Vitamin E	mg	1.6	12
Vitamin K	µg	7.3	55
Thiamine	µg	60	450
Riboflavin	µg	120	900
Vitamin B_6	µg	46	350
Vitamin B_{12}	µg	0.37	2.8
Niacin	mg	0.73	5.5
Pantothenic acid	mg	0.4	3.0
Biotin	µg	2.7	20
Folic acid	µg	8.6	65
Vitamin C	mg	10	75
Choline	mg	13	100
Carnitine	mg	1.5	11
Taurine	mg	4.8	36
Inositol	mg	6.4	48
Energy	Kcal (kJ)	280	505 (2,100)

This formula is low on proteins (2.2g/100 ml), while its carbohydrate content is increase to 6.6 g/100 ml (due to the introduction of lactose and maltose dextrine). A mixture of vegetable oils was also introduced to optimise the fats in the formula and to make it more similar to human milk.

RESULTS AND DISCUSSION

The children of both groups were subdivided into three sub-groups, depending on their SCORAD index.

In children with light dermatitis (SCORAD≤ 20), skin damage was restricted to the face and extremities. Their symptoms included erythema, isolated pimples, dryness. Medium-severe dermatitis (SCORAD 21- 40) was characterised by erythema, edema, lichenisation, considerable dryness, peeling and itch. Severe dermatitis (SCORAD ≥ 40) was characterised by more extensive skin damage: more severe erythema and edema, a large number of pimples, dampness, scabs, excoriation, and lichenification. Skin itching and sleep disturbance were also recorded.

Children with medium-severe and severe dermatitis prevailed in both groups studied. The control group included a greater number of severely afflicted children than the main group (Table 2). This was so because the control group included the children on whom previously used specialist hypoallergenic products had no beneficial effect.

Table 2. Groups in accordance with atopic dermatitis (M ± m)

Severity level	Groups	
	Main group (n = 41)	Control group (n=38)
Sub-group 1 SCORAD < 20	17.1 ± 0.8 n = 8	16.3 ± 0.8 n = 9
Sub-group 2 SCORAD > 40	31.2 ±1.1 n = 22	31.6 ± 2.5 n = 11
Sub-group 3 SCORAD >40	45.8 ± 2.2 n = 11	67.1 ± 3.7 n = 18

The study indicated that most children in the main group tolerated the product based on goat's milk. Their growth and development were good. The monthly average weight gain was 504 ± 81.1 g. Weight gain in the control group was lower (460±43.2 g). However, there were no reliable indications of difference.

After 1-3 weeks, 33 out of 41 children fed with the formula based on goat's milk went into remission. Hyperaemia, itch, rash, exfoliation and dampness

disappeared. Dryness of skin persisted in some children. Control group children, on whom products based on soy milk isolates and protein hydrolysates had no beneficial effect, also responded well to the product based on goat's milk. Most of the 38 children, who had been on a milk-free diet previously, went into remission (Table 3). The difference between the SCORAD indices of the main and control group children became insignificant after the treatment.

Table 3. SCORAD indices in children with atopic dermatitis before and after the treatment

Group	Period	SCORAD		
		Sub-group 1	Sub-group 2	Sub-group 3
Main	Before treatment After treatment	17.1 ± 0.8 7.8 ± 1.5	31.2 ± 1.1 9.4 ± 1.6	45.8 ± 2.2 22.7 ± 1.5
Control	Before treatment After treatment	16.3 ± 0.8 0	31.6 ± 2.5 10.2 ± 2.4	67.1 ± 3.7 18.7 ± 1.0

However, atopic dermatitis did not improve in 8 out of 41 main group children after they were transferred from cow's milk to the formula based on goat's milk. Later on, these children were transferred to a milk-free diet. After this, a remission was achieved.

Immunological testing showed an increase in general IgE in blood serum among half of the children in the main group. Among the control group children, the proportion of those with high IgE was higher (Table 4).

Table 4. Number of children with atopic dermatitis and their total and specific IgE and IgG antibodies

Group	Number of children	General IgE	Specific IgE	Specific IgE + IgG	Specific IgG
Main	n = 41	20	9	17	15
Control	n = 38	26	8	17	13
Total	n = 79	46	17	34	28

As is shown in Table 4, allergen-specific IgE and IgG antibodies to cow's milk and soy proteins increased in most main group children. For the control group, an increase of allergen-specific IgE antibodies to milk proteins was registered in half of the children, while allergen-specific IgG antibodies increased in number in one third of all children. The concentrations of specific Ig E and IgG antibodies in blood were higher in the children on a milk-free diet than in the main group children (Tables 5 and 6).

Table 5. General and specific IgE antibodies to cow milk and soy proteins in blood serum of children with atopic dermatitis before and after the course of treatment (M±m)

Group	Period	General IgE logME/ml	CMP, unit/ml	Casein, unit/ml	β-IG, unit/ml	Soy, unit/ml
Main n = 33	Before treatment	1.4 ± 0.09	0.6 ± 0.04	0.6 ± 0.06	0.6 ± 0.05	0.6 ± 0.06
	After treatment	1.4 ± 0.04	0.4 ± 0.03	0.3 ± 0.05	0.3 ± 0.04	0.4 ± 0.02
Control n = 38	Before treatment	1.7 ± 0.09	1.2 ± 0.2	1.1± 0.07	0.9 ± 0.04	0.7 ± 0.06
	After treatment	1.2 ± 0.08	0.6 ± 0.1*	0.3 ± 0.02*	0.4 ± 0.02*	0.3 ± 0.03

CMP: cow's milk protein, β-IG: β–lactoglobulin;
0-02 unit/ml: no allergy (+0);
0.3-0.6 unit/ml: light allergy (+1);
0.7-3.5 unit/ml: moderate allergy (+2);
3.6-17.0 unit/ml: severe allergy (+3)
* Differences in comparison with the same characteristic before the treatment are reliable ($p<0.05$).

Table 6. General and specific IgG antibodies to cow's milk and soy proteins in blood serum of children with atopic dermatitis before and after the course of treatment (M ± m)

Group	Period	CMP, unit/ml	Casein, μg/ml	β-IG, unit/ml	Soy
Main n = 33	Before treatment	5.8 ± 0.4	3.6 ± 0.2	3.8 ± 0.2	3.3 ± 0.2
	After treatment	2.8 ± 0.2*	1.1 ± 0.1*	1.2 ± 0.1*	0.6 ± 0.07*
Control n = 38	Before treatment	5.7 ± 0.2	4.2 ± 0.1	4.1 ± 0.2	4.7 ± 0.3
	After treatment	2.3 ± 0.1*	1.2 ± 0.1*	1.2 ± 0.1*	0.5 ± 0.1*

0-1.0 μg/ml: no allergy (+0);
1.1-3.0 μg/ml: light allergy (+1);
3.1-10.0 μg/ml: moderate allergy (+2);
10.1-30 μg/ml: severe allergy (+3)
* $p<0.05$.

It was established that, in the main group, allergen-specific IgE and IgG to cow's milk, casein, β-lactoglobulin and soy protein started to tend towards their normal values after 1.5-2 months of treatment. General IgG concentration in blood remained at the previous level.

In children kept on a hypoallergenic milk-free diet, general IgE as well as specific IgE and IgG antibodies to cow's milk, its components and to soymilk decreased. However no statistically reliable difference between the characteristics studied before and after the course of treatment was established in either group of children. It should be noted that although concentrations of specific antibodies to cow's milk were higher in the control group children before treatment, there was little difference between the two groups after treatment. For both groups these concentrations were near their normal values (Tables 5 and 6),

Immunological monitoring of the effect of the formula studied on toddlers with atopic dermatitis showed that it was positive, which was reflected by both IgE and IgG of allergen-specific antibodies to cow's milk.

Administering a hypoallergenic, milk-free diet resulted in a statistically meaningful reduction of general IgE as well as of specific IgE and IgG antibodies to the above food proteins.

An obvious positive effect was achieved with fortified 'Gold Nanny-Goat' as well as with a milk-free diet. However, the important advantage in using the formula based on goat's milk was that it provided the children with a host of essential micronutrients (calcium, vitamin B_2, folic acid, iron etc.). The level of these nutrients might be low in children on a milk-free diet. Consequently, one can recommend a milk-free diet only to those toddlers who have not improved with the available hypoallergenic products. Also, a milk-free diet should be prescribed for short periods only.

Thus, the results show that substituting products based on goat's milk for those based on cow's milk in the diet of toddlers with atopical dermatitis can be an optimum solution. This study proves that the new class of products based on goat's milk should be included in the children's diet as part of a comprehensive treatment of an allergy to cow's milk proteins as well as for prevention of food allergies in early childhood.

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