



SHIMA ZONUBI

PharmD

30th October

**Iranian Society of Pediatric
Gastroenterology & Hepatology**



NUTRITIONAL MANAGEMENT IN GASTROINTESTINAL PROBLEMS

✓ LACTOSE INTOLERANCE

✓ REFLUX

✓ CONSTIPATION



HUMAN MILK

is the best nutrition
in this critical period. According
to WHO baby should exclusively
breastfed for the first six months
of life



BUT
if breastfeeding is not possible, or
Human Milk is not available,
Infant Formulas are specially
designed as a safe alternative



Bebelac Formulas:
Ensures Optimal Growth and
Development & provide precise
nutrition for GUT HEALTH
(Easy Digestion)



Healthy Tummy, Happy Baby

ببلاک
Bebelac®

محصولات پایه Regular



FOCUSED ON GUT HEALTH, WELLBEING & GROWTH

Bebelac Formula Strength points:

1. Functional benefits which are related to non-mandatory ingredients
2. Following strict Quality & Safety Regulations
3. In line with the latest Nutritional Standards
4. Credible clinical evidence on the formulas



SCGOS/LCFOS (9:1), AN APPROPRIATE CHOICE OF PREBIOTICS IN BEBELAC INFANT FORMULA

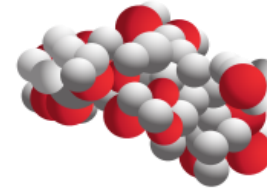
The unique prebiotic oligosaccharide mixture scGOS/lcFOS (9:1)

- Developed in 1994 ,patented in 1998, added to infant formula in 2000
- Amounts and molecular size and distribution similar to HMOS* (0.8 g/100 ml, GOS:FOS 9:1)
- Made from natural ingredients (lactose and chicory)
- With similar functions of HMOS

Aim:

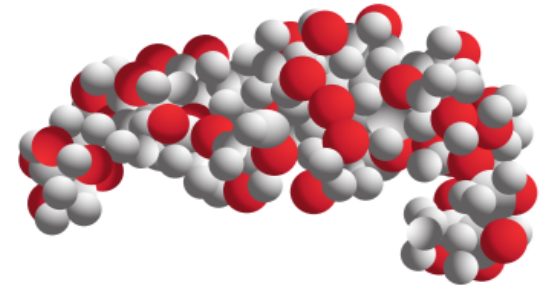
Healthy gut microbiota similar to breast-fed infants, resulting in health benefits

scGOS
90%
short-chain
 β -Galacto-OligoSaccharides from lactose



Gal(β1-4)Gal(β1-4)Glc

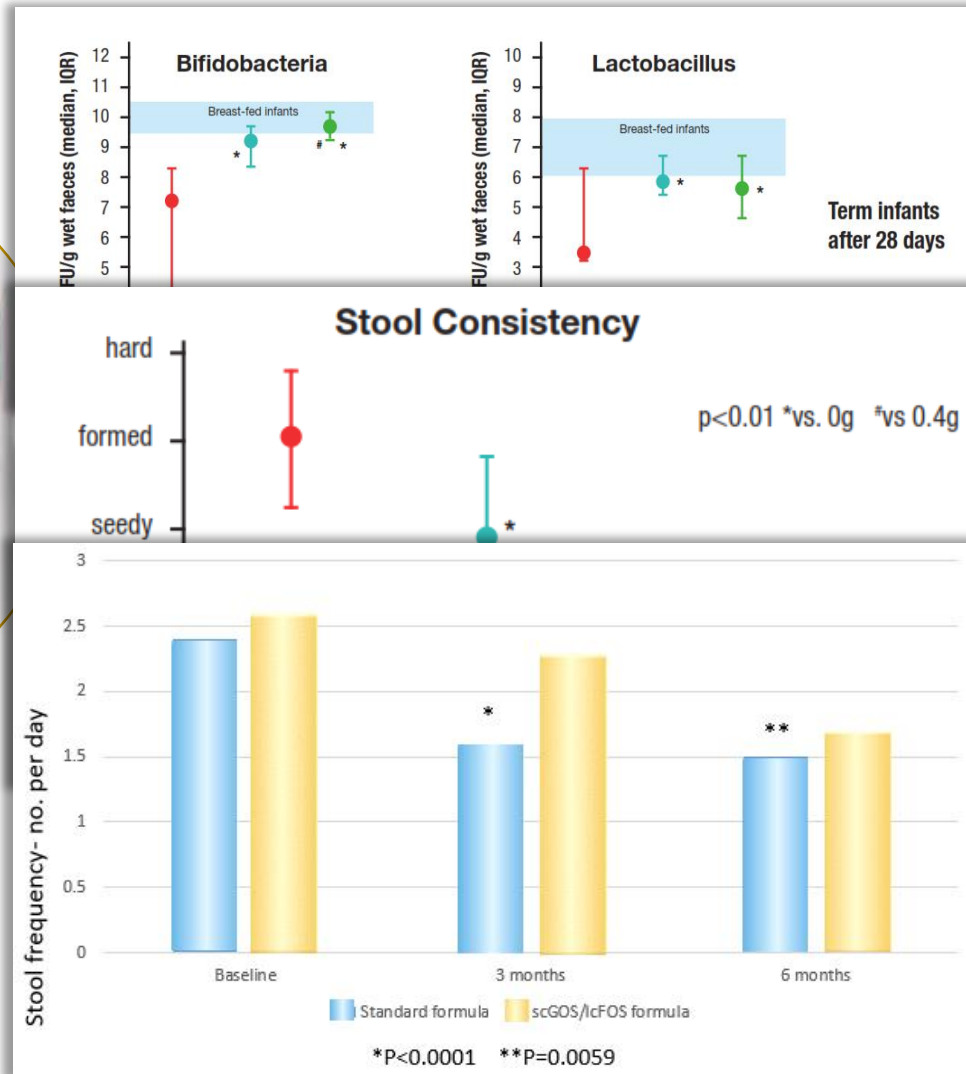
lcFOS
10%
long-chain
 β -Fructo-OligoSaccharides from chicory



[Frc(β2-1)]₈Frc(β2-1)Glc

* HMOS: Human Milk Oligosaccharides

SCGOS/LCFOS (9:1), AN APPROPRIATE CHOICE OF PREBIOTICS IN BEBELAC INFANT FORMULA



Has a dose-dependent effect on the growth of bifidobacteria & lactobacilli in the intestine

Promotes softer stools close to the breastfed infants

Significant increase in stool frequency



The Most Complete Range Of Tailored Nutrition For Gut Health

LACTOSE INTOLERANCE

Bebelac Lactose Free

For dietary management of lactose intolerance and diarrhea

From birth onwards

Contains all the nutrients for optimal growth & development



BEBELAC LF



Optimum Diarrhea Dietary Management

- 100% Lactose free*, No sucrose
- Maltodextrin for better absorption
- Optimum level of Zinc
- Low osmolarity (150 mOsm/L) for better tolerance

Optimum Digestion

- A combination of w/c protein (60/40) for better digestion
- Similar Amino Acids profile to human milk

Optimum Immune Support

- Nucleotide
- Vit A,D,C
- Zn
- Se

Optimum Brain, Visual & Bones Development

- LCP (AA/DHA)
- Fe ,Iodine, Taurine
- Vit D Ideal Ca/P: 1.8

*According to EC lactose free formula contains less than 0.01g/100kcal of lactose

**Shorter
duration of
diarrhea**

**Better
weight gain**

**Less stool
frequency**



CLINICAL STUDY ON BEBELAC LF

Aim: compare the effect of a lactose-free and a lactose-containing formula in dietary management of acute childhood diarrhea

PATIENTS AND METHOD:

During 2 years

A randomized, double-blind clinical trial

Inclusion criteria

- 80 male children, Formula-fed, aged 3 to 24 months
- With acute watery diarrhea (no more than 7 days) and mild or moderate dehydration
- Children were kept in hospital for at least 48 hours
- Data were collected on admission , at 4, 24 and each following 24 h period:
- Body weight, Stool frequency and consistency, Stool weight , Volume of ORS,
- Formula and rice gruel consumed
- After discharge, parents were asked to record the timing, frequency and consistency of stool at home for another 2 consecutive days
- If children presented with diarrhea, study continued for another 2 days
- Total duration of children's participation in the study was 7 days



CLINICAL STUDY ON BEBELAC LF

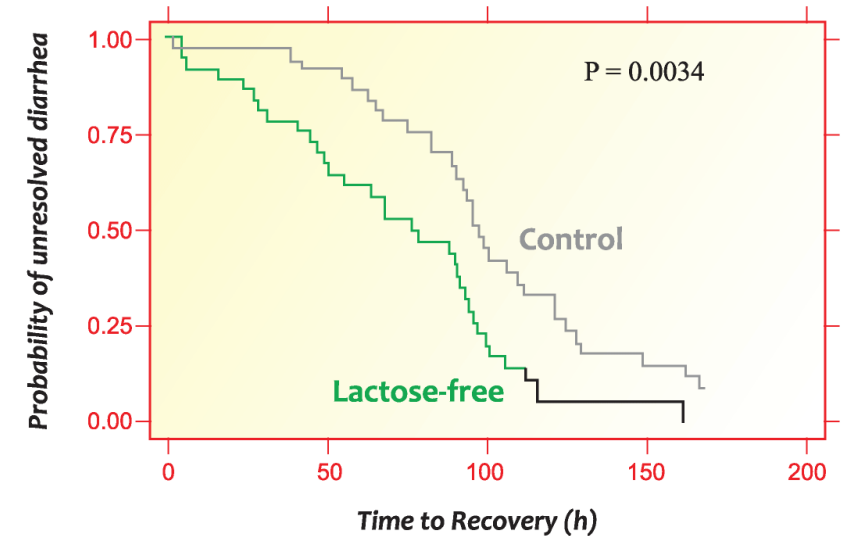
Results

- Demographic and clinical characteristic of the 2 groups were comparable at the enrollment
- Rotavirus was identified in approximately 50% of the children in each group
- The number of unscheduled intravenous infusions were twice in control group compare to treatment group
- 3 children in the control group did not resolve from diarrhea within 7 days of treatment

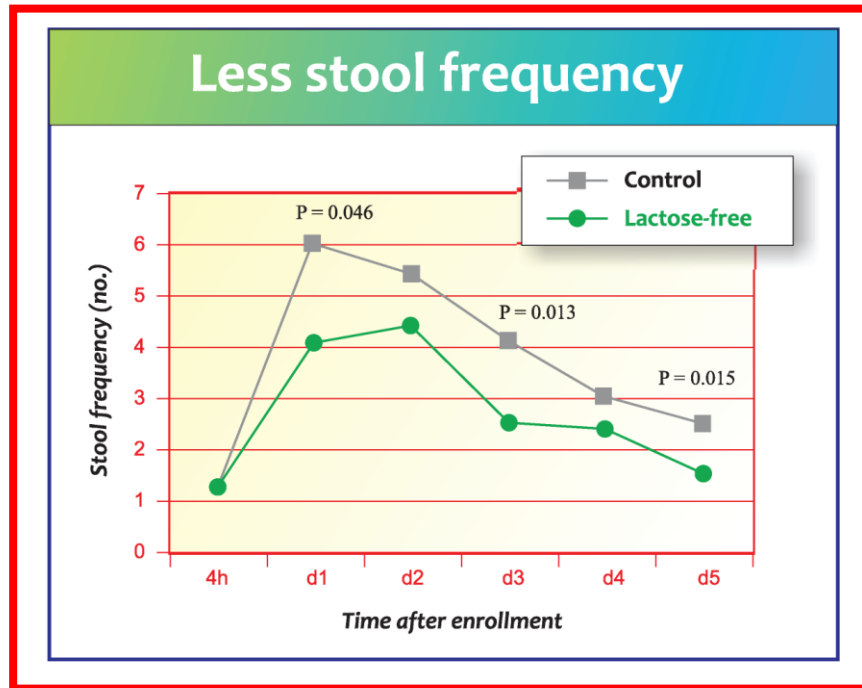
Using survival analysis, the **median duration** of diarrhea was significantly shortened by 20.5 hours in the treatment group compared to the control group (77.0 hours in the treatment group vs. 97.5 hours in the control group; $P = 0.002$).

Mean duration of diarrhea reduced significantly in treatment group compared to control group (64.2 ± 39.9 vs 92.0 ± 43.3 h, $P = 0.003$)

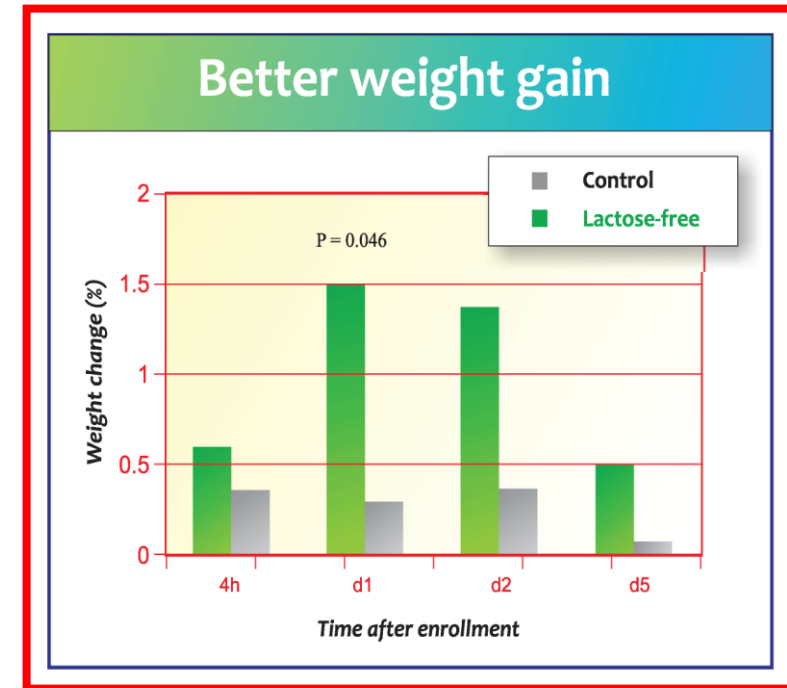
Shorter duration of diarrhea



CLINICAL STUDY ON BEBELAC LF



- The **stool frequency** was significantly decreased in treatment group on day 1, 3 and 5, $P=0.046$, 0.013 , 0.015



- Significant increase in **weight change** of children in the treatment group at 24 hr was observed (1.51 ± 1.71 vs 0.31 ± 1.98 percent, $P=0.005$)

- Vomiting after refeeding was more frequent in control group (50% vs. 20.5%, $P=0.005$)
- Acidosis cleared up to near normal in treatment group at 24hr, moderate acidosis persisted in the control group, $P=0.0015$)
- Similar results were obtained from analysis of children infected with rotavirus

EFFICACY OF LACTOSE-FREE FORMULA AS A 24-HOUR MANAGEMENT APPROACH FOR ACUTE DIARRHEA AMONG CHILDREN

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Abstract

Background: Diarrhea continues to be a prominent contributor to morbidity and mortality among young children under five years, especially in developing nations. Secondary lactose intolerance is a significant complication that can arise from acute diarrhea. However, it can be effectively managed with lactose-free formula.

Objective: This study aimed to compare the rate of diarrhea resolution within a 24-hour period among children receiving lactose-free formula and those receiving lactose-containing formula.

Methods: This retrospective cohort study took place at Naresuan University Hospital and included 153 children aged between one month and five years admitted with acute diarrhea. Participants with bloody mucous diarrhea suspected to be bacterial in nature, positive stool culture, breastfeeding and chronic diarrhea (including cow's milk protein allergy and inflammatory bowel disease) were excluded. We compared the effectiveness of lactose-free formula (n=48) and lactose-containing formula in improving clinical diarrhea within a 24-hour (n=105).

Results: The study findings indicated the lactose-free formula group demonstrated a statistically significant increase in efficacy, with a 3.90 fold improvement in diarrhea within 24 hours compared with that of the group receiving lactose-containing formula. These results were obtained after the confounding factors were adjusted using multivariable regression analysis. The adjusted relative risk (RR) for a 24-hour improvement in diarrhea was 3.90 (95% CI: 1.91-7.95). However, this study encountered limitations regarding the sample size and accurate measurement of stool output.

Conclusion: Lactose-free formula showed the potential for greater effectiveness in improving acute diarrhea within a 24-hour timeframe compared with lactose-containing formula.

Keywords: Acute diarrhea, Lactose intolerance, Lactose-free formula

J Southeast Asian Med Res 2023; 7:e0175

<https://doi.org/10.55374/jseamed.v7.175>

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Received: 27 May 2023

Revised: 21 June 2023

Accepted: 26 June 2023



153 children aged between one month and five years admitted with acute diarrhea.



The lactose-free formula group had a **3.90** fold higher rate of improvement than that of the lactose-containing formula group.



75% of participants receiving lactose-free formula demonstrated improvement within 24 hours.



- This study

provides evidence supporting the

SUPERIOR EFFICACY

of lactose-free formula compared with lactose-containing formula in the dietary management of acute viral diarrhea among children aged 1 month to 5 years old, within a 24-hour timeframe.

REFLUX

Bebelac AR

Anti reflux

From birth onwards

Contains all the nutrients for optimal growth & development

✓ Thickened with Locust
(Carob) bean gum LBG
(0.4 g/100ml)

✓ Contain scGOS/lcFOS
(0.4 g/100ml)



Bebelac AR

Bebelac AR thickened with LBG compared to standard formula shows clinically significant;

- ✓ Decreased severity in reflux
- ✓ Fewer episodes of reflux
- ✓ Decreased frequency of reflux
- ✓ PH normalization



And also provides:

- ✓ Good Appetite
- ✓ Normal Growth
- ✓ Normal sleeping habits
- ✓ No more Respiratory problems

Bebelac AR

Bebelac Anti-Reflux is the most extensively investigated anti-reflux formula on the market worldwide, which provides pediatricians with the evidence they need to recommend it.



Overview of clinical studies
have been carried out on

Authors	Study quality	Selection of participants	Groups	Observation period	Advantages of the Anti-Reflux (AR) group vs. reference group
Wenzl <i>et al.</i> 2003	RCT with cross-over design	Infants with frequent regurgitation. Age < 4 months	AR/control (n=14)	6 feeding intervals. Change of formula after each feed	• Reduction in severity of regurgitation • Regurgitation less often • Reflux less often
Grosse <i>et al.</i> 1998	RCT with cross-over design	Infants with frequent regurgitation. Age between 1 week and 4 months	AR/control (n=10)	12 days. Change of formula after 6 days	• Regurgitation less often • Reflux less often
Borrelli <i>et al.</i> 1997	RCT	Infants with frequent regurgitation. Age < 4 months	AR (n=12) Rice starch (n=12)	2 weeks	• Reduction in severity of regurgitation • Regurgitation less often • Reflux less often
Vandenplas <i>et al.</i> 1994	RCT	Infants with frequent regurgitation. Age between 1 week and 4 months	AR (n=10) Control (n=10)	1 week	• Reduction in severity of regurgitation • Reduction in exposure of the oesophagus to acid

ESPGHAN recommends thickening the formula
(Vandenplas Y et al., 2009):

In the case of gastro-esophageal reflux (GER) without complications and with no symptoms, thickening the formula with carob bean gum, has proved to be a successful way of improving quality of life.

CONSTIPATION

Bebelac Comfort

For dietary management of colic & constipation

From birth onwards

Contains all the nutrients for optimal growth & development



BEBELAC COMFORT



**Structured lipids
 β -palmitate**

- Improve**
- Stool consistency
 - Fat and calcium absorption

**Partially Hydrolysed protein
(100% whey)**

- Improve Colic
- Easy digestibility
- Improve Stool consistency

**Prebiotics
(GOS/FOS)**

- Stool consistency
- Stool frequency
- Healthy intestinal flora

Starch & reduced lactose

- Less possetting
- Satiety value

BEBELAC COMFORT

No other "comfort formula" on the market has such comprehensive clinical evidence

Overview of clinical studies of the health effects of bebelac Comfort

Authors	Study quality	Selection of participants	Groups	Observation period	Advantages of the AR group vs. reference group
Veitl et al. 2000	RCT	Infants with at least one of the following symptoms: excessive crying, functional constipation (with or without cramps), general abdominal discomfort and spitting up	Bebelac Comfort (n=34), Control (n=17)	2 weeks	• Improvement in overall symptoms, abdominal discomfort and crying (with cramps) after just 1 w
Schmelzle et al. 2003	RCT	Healthy infants born at full term. Aged under two weeks	Bebelac Comfort (n=49), Control (n=53)	6 and 10 weeks	• Softer, more frequent stools • Higher proportion of bifidus bacteria in the stools
Savino et al. 2003	Prospective observational study	Infants with colic, symptoms of spitting up and/or constipation. Aged under 3 months	Bebelac Comfort (n=604)	2 weeks	• Reduction in colic • Reduction in spitting up • Reduction in constipation • Positive assessment of formula from 91% of parents and 95% of paediatricians
Savino et al. 2005	RCT	Infants with functional constipation and/or symptoms of spitting up. Aged up to 4 months	Bebelac Comfort (n=55), Control (n=40)	2 weeks	• More frequent stools after just 1 week • Reduction in spitting up after just 1 week
Savino et al. 2006	RCT	Infants with colic. Aged up to 4 months	Bebelac Comfort (n=103), Control (n=93)	2 weeks	• Reduction in infantile colic after just 1 week
Bongers et al. 2007	RCT with cross-over design	Infants with constipation. Aged between 3 and 20 weeks	Bebelac Comfort /control (n=38)	6 weeks. Change of formula after 3 weeks	• Softer stools

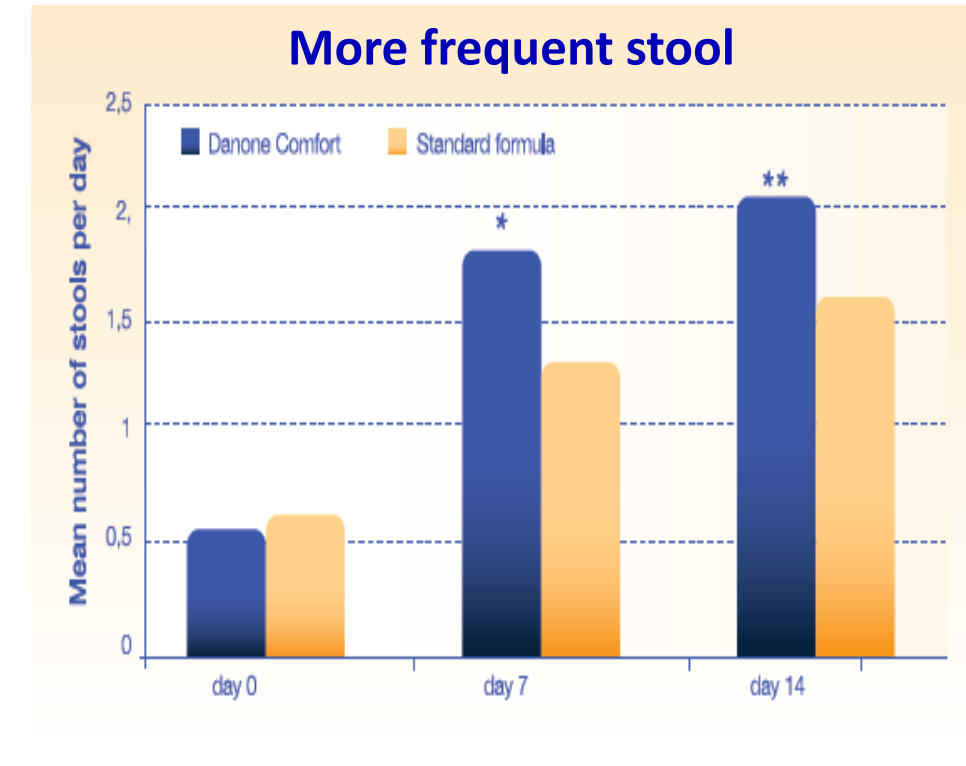
A Randomized Double-Blind Study

Improved frequency of stools in infants with constipation

- Included 168 full term infants aged up to 4 months
- With functional constipation (< 1 bowel movement/day) and/or symptoms of spitting up (>3 times/day)
- Infants were given Bebelac Comfort or conventional formula for 2 weeks.
- ✓ After 1 week, the frequency of stools had improved in both groups, with a significantly higher figure in Bebelac Comfort group
- ✓ After 2 weeks, the frequency of stools was still significantly higher in Bebelac Comfort group, at about 2 per day.

The researchers concluded that Bebelac Comfort reduces FGIDs in infancy and improves intestinal tolerance in the first few months of life

NUMBER OF STOOLS INCREASED SIGNIFICANTLY IN 7 DAYS

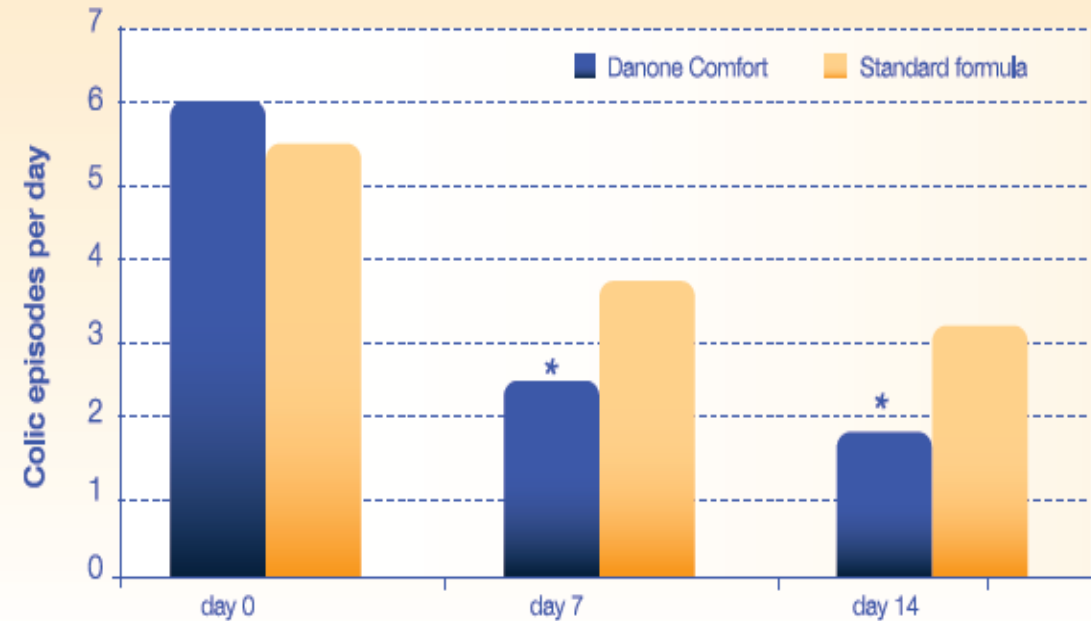


Reduction of crying episodes owing to infantile colic: a randomized controlled study...

Bebelac comfort provides comprehensive relief from digestive discomfort

- Prospective, randomized, placebo-controlled study
- Included 199 full term infants aged up to 4 months, suffering from colic
- Parents recorded the number of episodes of colic/day for 2 weeks using a questionnaire.
- Infants were given Bebelac Comfort or conventional formula and Simeticon for 2 weeks.
- ✓ After 1 week: a significantly greater reduction in symptoms in the Comfort group than in the control group.
- ✓ After 2 weeks: symptoms of infantile colic subsided even further, with a significantly greater reduction in Comfort group.

70% REDUCTION IN COLIC EPISODES WITHIN 14 DAYS



HAPPINESS
STARTS
IN THE
TUMMY

ببلاک
Bebelac

