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THE EFFICACY AND SAFETY OF COLIC CALM®

A Clinical Study Evaluating the
Effect of Colic Calm on Infants

The background of the lower half of the page is a solid yellow color. It is decorated with several stylized, rounded cloud shapes in a slightly darker shade of yellow. These clouds are scattered across the page, with some overlapping. The overall aesthetic is clean, bright, and child-friendly.

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INTRODUCTION

Infant crying, specifically during the newborn phase, varies significantly from baby to baby. It is fairly common for infants to go through periods where they appear abnormally irritable, fussy or seem to cry for extended periods without reason. However, the pattern and amount of crying define the physiological and pathological nature of distress caused to the infant. Colic—a paroxysmal, spontaneous, inconsolable, and unpredictable crying without an identifiable cause in an otherwise healthy infant—affects an estimated 10-40% of infants globally.¹ Although infant colic usually resolves itself after the baby is three to four months old, it is associated with significant parental distress. Colic is the most frequently reported reason for pediatric outpatient visits.² Therefore, it poses a substantial burden to families, health professionals, and the health care system.

To date, there is no single effective treatment for colic. A practical and acceptable intervention would represent a significant advancement in clinical practice. Colic Calm® is one such intervention with 100% natural ingredients and has been proposed to ease babies' discomfort associated with colic.

This open-label trial primarily aimed to determine whether Colic Calm benefits colicky infants <4 months old by reducing the daily crying time. Secondary objectives were improved sleep patterns, relapse of colic symptoms, and the safety outcome.

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ABSTRACT

This document outlines a summary of the findings from a clinical study conducted to evaluate the efficacy and safety of Colic Calm, a new infantile formula to ease infantile colic.

The study took place over a course of 21 days. Thirty participants were examined with results being reported at the 7-day mark and 14-day mark following continued use of Colic Calm.

Objectives of this study include evaluating the effect of Colic Calm administration on the following in infants:



Reduced Daily Crying Time



Improved Sleep Patterns



Relapse of Colic Symptoms



Safety Outcome

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BACKGROUND

A little bit about Colic Calm.

At Colic Calm, we believe in using the highest quality natural ingredients to create products that empower families to be their best, and healthiest selves.

Active ingredients in Colic Calm are:

- **Prunus spinosa (Blackthorn)**
- **Carum carvi (Caraway)**
- **Matricaria chamomilla (Chamomile)**
- **Foeniculum vulgare (Fennel)**
- **Zingiber officinale (Ginger)**
- **Melissa officinalis (Lemon Balm)**
- **Mentha piperita (Peppermint)**
- **Carbo Vegetabilis (Vegetable Carbon)**

It is also free from sugar, allergens, animal products, sodium bicarbonate, simethicone, artificial flavors, or colors. Given its safe and effective formulation, Colic Calm is the leading effective medicine for infant colic, gas, and reflux.

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REDUCED DAILY CRYING TIME

Evaluating the effect of Colic Calm administration on daily crying time in infants.



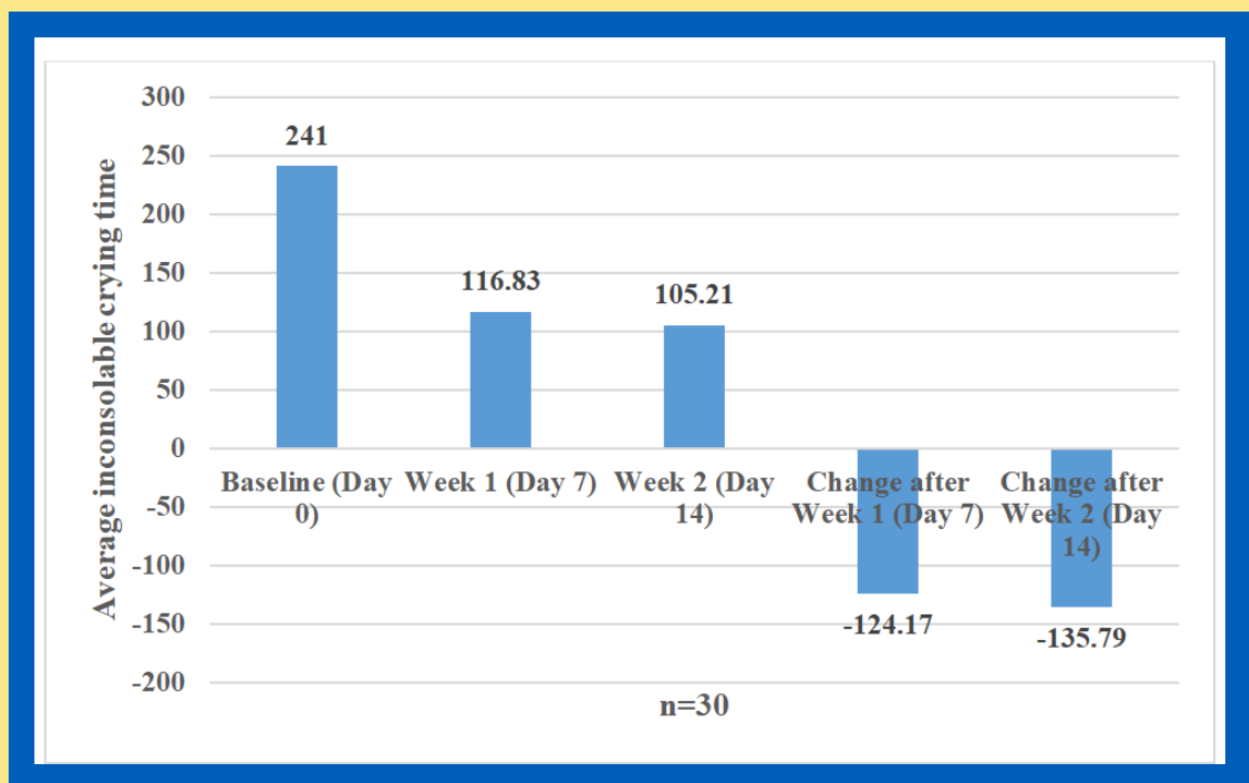
Babies cried an average of 2.27 hours less per day after using Colic Calm.

Overall, average inconsolable crying time was reduced by more than 50% after one week of administration of Colic Calm, which further improved during the second week. This finding suggests that Colic Calm was capable of reducing daily crying time in infants who consumed it for 14 days.

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Effect of Colic Calm on Average Inconsolable Crying Time

On Day 0, infants with colic symptoms cried for an average of 241 minutes per day. On Day 7 after Colic Calm administration, that number decreased to an average of 116.83 minutes per day with roughly 73% of the participants responding. And on Day 14 after continued Colic Calm administration, that number decreased to an average of 105.21 minutes per day with 80% of the participants responding.



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IMPROVED SLEEP PATTERNS

Evaluate the effect of Colic Calm administration on improvement in sleeping patterns of infants.



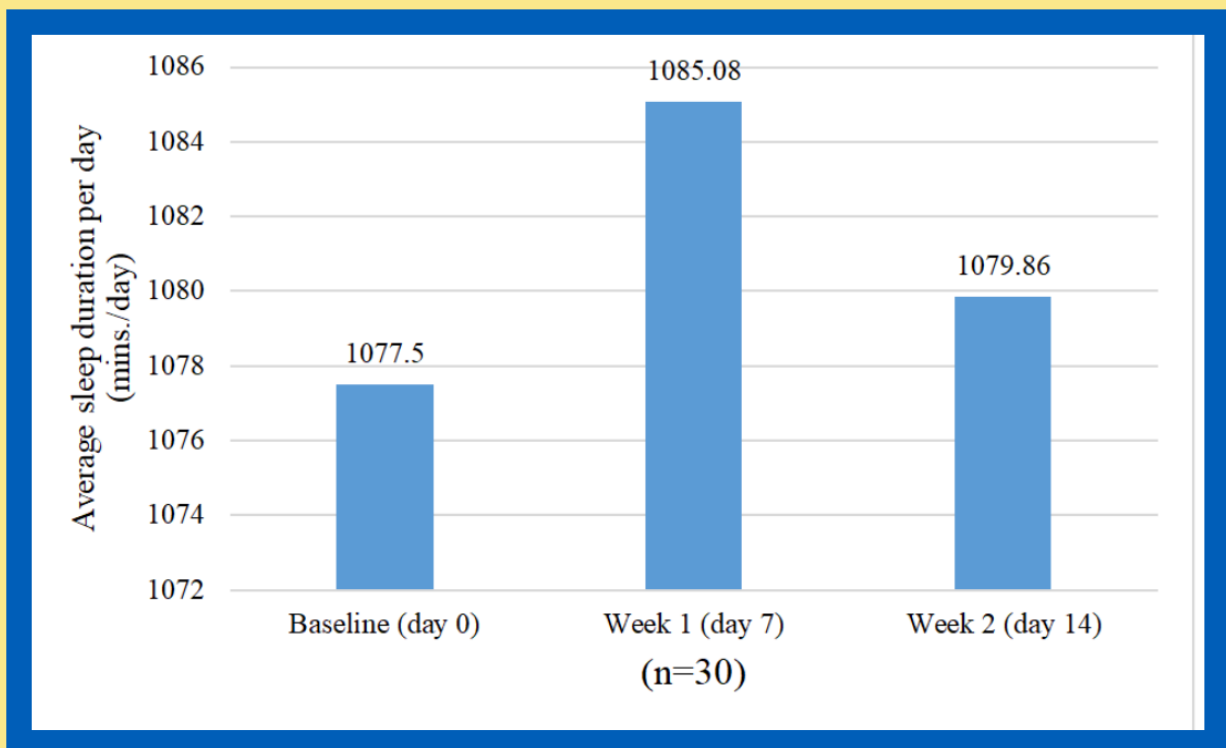
Colic Calm supported healthy sleep patterns in babies.

Treatment showed no further degradation in sleep. Due to abatement of colic symptoms, sleep was either maintained or improved.

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Effect of Colic Calm on Average Sleep Duration

On Day 0, infants slept an average of 1077.5 minutes per day. On Day 7 after Colic Calm administration, infants slept an average of 1085.08 minutes per day. On Day 14 after continued Colic Calm administration, infants slept an average of 1079.86 minutes per day.



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RELAPSE OF COLIC SYMPTOMS

Evaluate the effect of Colic Calm administration on the relapse of colic symptoms in infants.



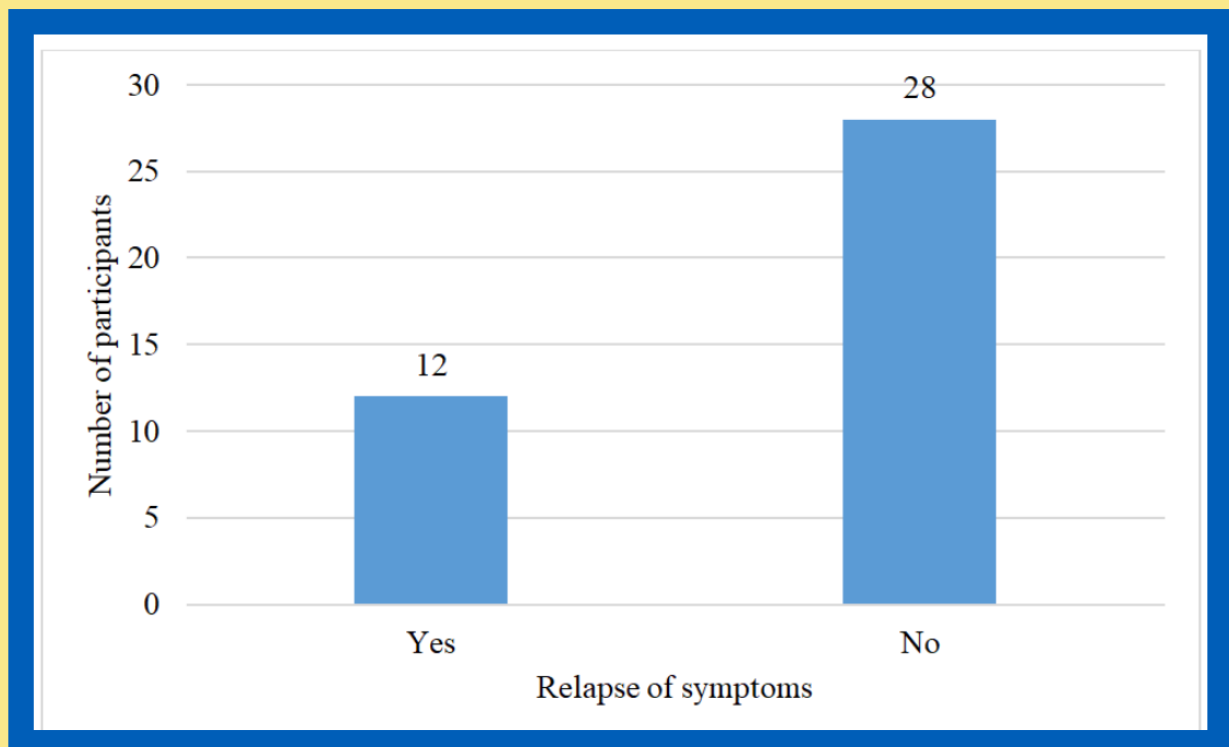
60% of babies who used Colic Calm did not have a relapse of colic symptoms.

Majority of the infants (60%) did not have a relapse of colic symptoms after the 7-day follow-up mark.

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Effect of Colic Calm on Relapse of Symptoms

After the intervention, only 12 infants were reported to have a relapse of colic symptoms while 28 infants were reported to not have a relapse of colic symptoms.



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SAFETY OUTCOME

Evaluate the effect of Colic Calm administration on the safety outcome measures including product tolerability and change in vital signs.



Unlike some over-the-counter medications, Colic Calm's safe and gentle formula did not have negative side effects.

There was a "good" tolerance of Colic Calm after the end of the second week.

Vital signs, body temperature and heart rate, were recorded at Day 0 and Day 14. There were no significant change in any vital signs observed during the study duration.

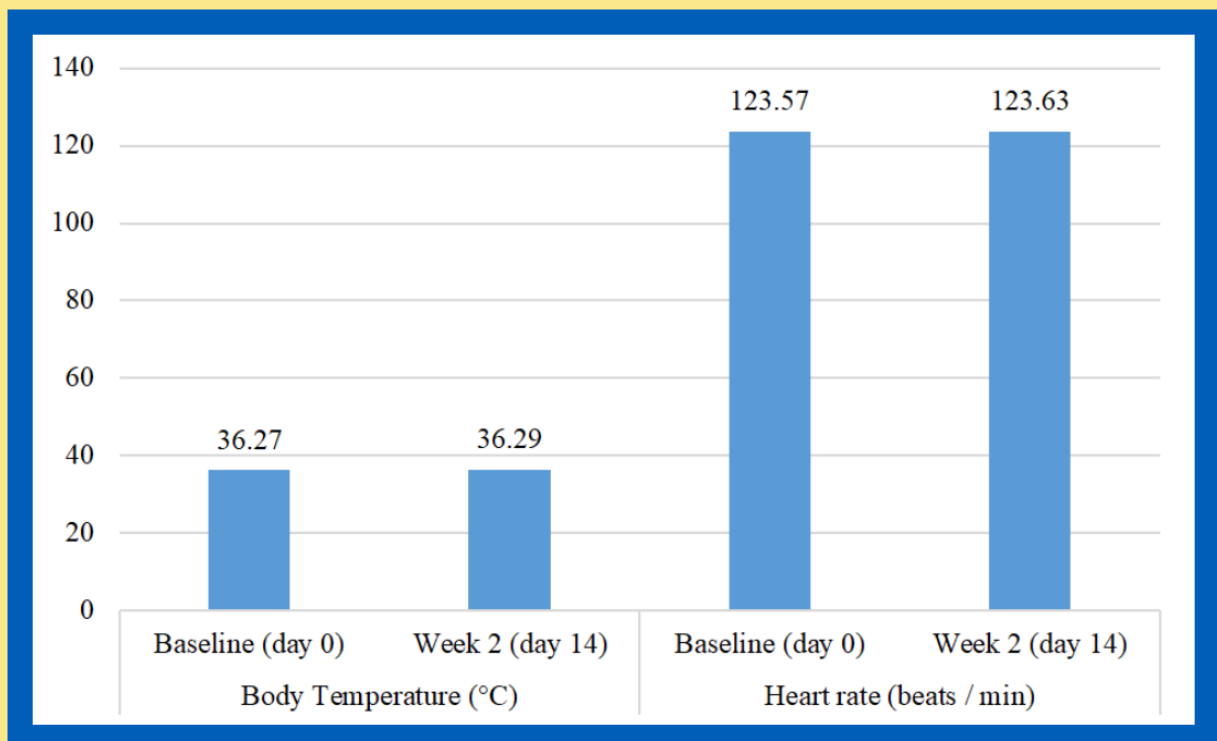
No serious adverse event was reported during this study.

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Effect of Colic Calm on Vital Signs

On Day 0, body temperature was reported to be an average of 36.27 degrees Celsius. On Day 14 after Colic Calm administration, it was reported to be an average of 36.29 degrees Celsius.

On Day 0, heart rate was reported to be an average of 123.57 beats per minute. On Day 14 after Colic Calm administration, it was reported to be an average of 123.63 beats per minute.



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CONCLUSION

The current study has been conducted for the scientific validation of the efficacy and safety of Colic Calm in reducing the distress and discomfort to infants caused by colic. The study results successfully prove that claim.

Results of the study concluded:

- **Colic Calm demonstrated a highly significant effect in reducing the daily inconsolable crying time of infants aged 3 - 16 weeks when administered for 14 days.**
- **Majority of the infants responded to Colic Calm within the first week of its administration and did not have a relapse of colic symptoms.**
- **Colic Calm supported healthy sleep patterns in babies.**
- **When compared with other over-the-counter medications on the market, the effect size of Colic Calm was equivalent or better without any side effects and a good tolerability index as rated by the parents or caregivers.**

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CITATIONS

- 1 Johnson JD, Cocker K, Change E. Infantile Colic: Recognition and Treatment. *Am Fam Physician*. 2015;92(7). Accessed November 22, 2021. www.aafp.org/afp
- 2 Biagioli E, Tarasco V, Lingua C, Moja L, Savino F. Pain-relieving agents for infantile colic. *Cochrane Database Syst Rev*. 2016;2106(9) doi: 10.1002/14651858.CD009999.PUB2