Synbiotic in the management of infantile colic: A randomised controlled trial

**Objective**
To study the effects of an oral, 7 strain synbiotic preparation in the management of infantile colic.

**Multi-strain formula used:**
- **Live bacteria:**
  - *Lactobacillus casei* PXN 37
  - *Lactobacillus rhamnosus* PXN 54
  - *Streptococcus thermophilus* PXN 66
  - *Lactobacillus acidophilus* PXN 35
  - *Bifidobacterium breve* PXN 25
  - *Lactobacillus delbrueckii ssp. bulgaricus* PXN 39
  - *Bifidobacterium infantis* PXN 27

**Methods**
This was a randomised, double blind, placebo controlled prospective parallel arm study in fifty infants aged 2 weeks to 4 months diagnosed with infantile colic as defined by Wessel’s criteria. The infants were randomly assigned to receive placebo or the synbiotic mixture for 30 days. The primary objective was treatment success, defined as reduction in average daily crying of at least 50% and the secondary objective was resolution of symptoms, defined as an average 90% reduction in daily crying. The primary and secondary endpoints were measured at 7 days after starting treatment and at 30 days, using symptom diaries completed by the parents.

**Results**
The two groups were comparable, with no difference seen in baseline characteristics. Treatment success was significantly higher in the synbiotic group (82.6%) compared with the placebo group (35.7%), at day 7 (p < 0.005). This difference was maintained at day 30 with a treatment success of 87% and 46% in the synbiotic group and placebo group, respectively (p < 0.01). In addition, symptom resolution was significantly higher in the synbiotic group (39%) compared to the placebo group (7%) at day 7 (p < 0.03). This trend continued to day 30 where 56% symptom resolution was experienced in the synbiotic group, compared to only 36% in the placebo group (P = 0.24). No adverse events were reported.

**Conclusion**
This study provides evidence that the 7 strain synbiotic mixture used can help to effectively manage symptoms of infantile colic without any reported side effects. The study supports the case for larger trials to assess whether it can also prevent infant colic.

**Outcomes after 7 days of Treatment**
- **Placebo Group**
  - % Treatment Success: 35.7%
  - % Complete Resolution of Symptoms: 7%
- **Synbiotic Group**
  - % Treatment Success: 82.6%
  - % Complete Resolution of Symptoms: 39%

**Outcomes after 30 days of Treatment**
- **Placebo Group**
  - % Treatment Success: 46%
  - % Complete Resolution of Symptoms: 36%
- **Synbiotic Group**
  - % Treatment Success: 87%
  - % Complete Resolution of Symptoms: 56%

**Full Reference:**

These specific 7 probiotic strains used in this trial can be found in Bio-Kult Infantis.

www.bio-kult.com

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