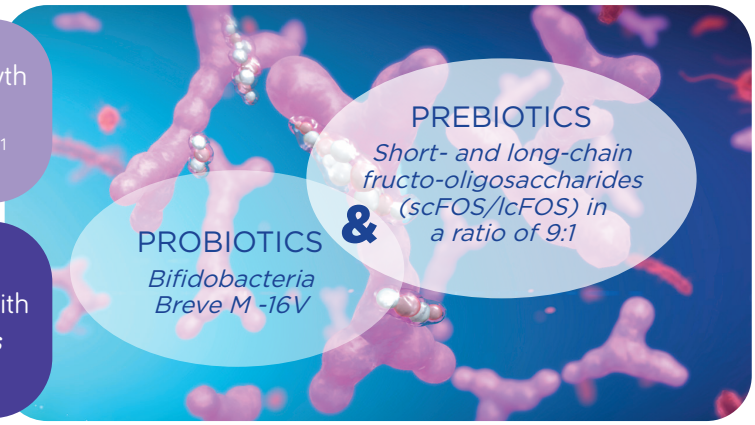
Boosting Immunity of Cow's Milk Protein Allergy Infants with *Synbiotics*

Infants with Cows' Milk Protein Allergy (CMPA) often have an altered gut microbiota compared to healthy breastfed infants[1-3] and are more susceptible to infections.[4-6] This microbial dysbiosis may negatively affect the development of an infant's immune system.[3]

Neocate Syneo is the only amino acid formula with synbiotics (AAF+Syneo) able to rebalance the gut microbiota of infants with CMPA making it more like that of a healthy breastfed infant.[3,7,8,9]

Synbiotics support the growth and establishment of beneficial Bifidobacteria.[9,11]

Neocate Syneo helps rebalance gut microbiota with ***fewer reported infections & antibiotic usage.***[9-11]



PRESTO TRIAL

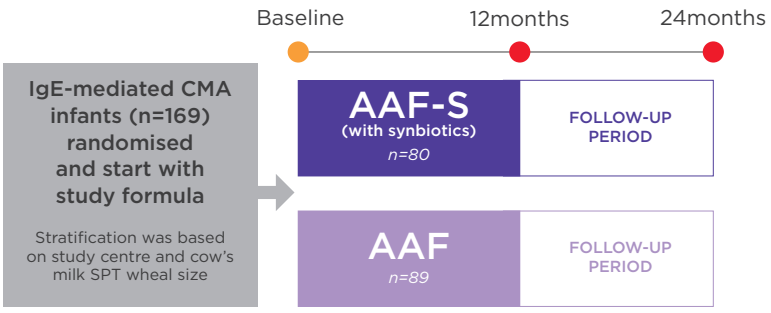
The first RCT to investigate the trajectory of CMP tolerance development and safety of **AAF+Syneo**. Infants < 13 months with confirmed IgE-mediated CMPA, were randomised to receive **AAF+Syneo** (n=80) or AAF (n=89) for 12 months, with a 2-year follow-up. The study was conducted at 20 sites in Germany, Italy, Singapore, Thailand, the United Kingdom, and the United States of America.

Results

AAF+Syneo is SAFE & SUITABLE for the dietary management of infants with IgE-mediated CMPA, who develop tolerance to Cows' milk protein at a similar trajectory compared to interventions with different hypoallergenic formulas and those without synbiotics.[1,9]

AAF+Syneo is effective in managing allergy symptoms, promoting normal growth and a healthy gut microbiome.[10]

Double-Blind Randomised Controlled Trial Design



During the study adverse events and serious adverse events were collected.

AAF: Amino-acid based formula
CMA: Cow's milk allergy
SPT: Skin prick test
Open food challege or anaphylactic history
Double-blind placebo controlled food challenge

Tolerance Development

There were **no significant differences** at 12 and 24 months in percentages of infants who developed tolerance.

	12 months	24 months
AAF-S (with synbiotics)	45%	64%
AAF	52%	59%

- **Half of all infants** became tolerant to cow's milk at 12 months. An additional 13% developed tolerance at 24 months.
  Numbers are in line with reported tolerance development trajectory.
- During the 12 months intervention, fewer infants hospitalised due to serious adverse events categorised as infections (9% vs 20% in AAF; p=0.036).

Infants have fewer infections, less medication use, and fewer hospital admissions with AAF+Syneo.[9-11]

SUMMARY OF CLINICAL STUDY RESULTS IN NEOCATE SYNEO

SAFETY AND EFFICACY

Growth, safety & hypoallergenicity were demonstrated in infants with IgE or non-IgE mediated CMPA.[3,7,8,10,12]

+

GUT MICROBIOTA

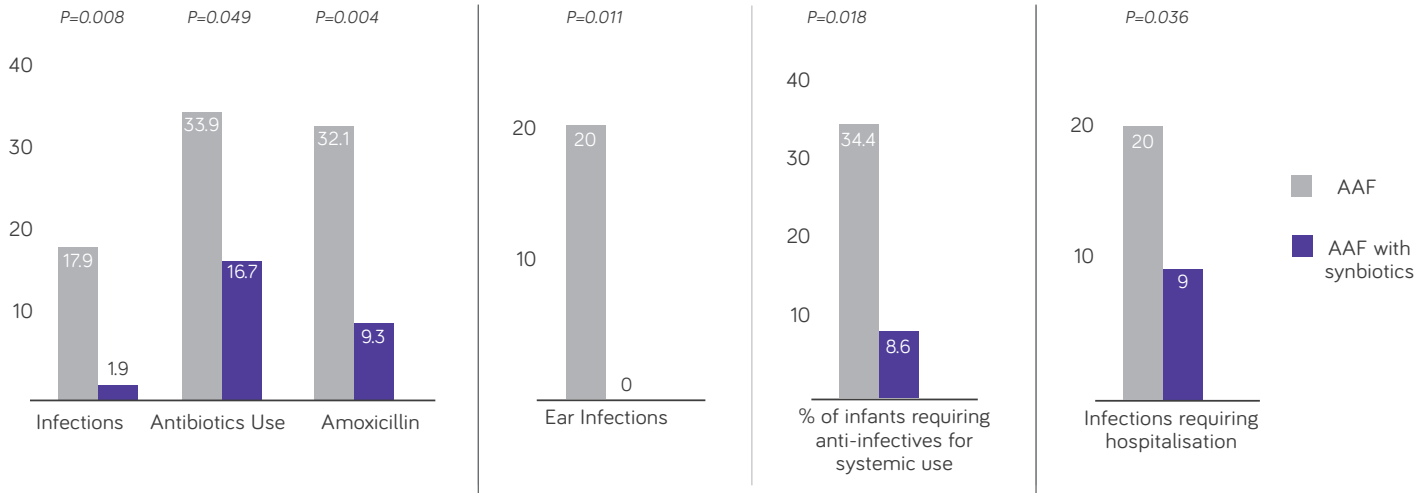
Infants have fewer infections, less medication use, and fewer hospital admissions with AAF+Syneo.[9]

+

IMMUNE SYSTEM

Gut bacteria closer to that of healthy breastfed infants, with increased levels of Bifidobacteria and reduced levels of clostridial groups.[9,10]

INFECTION OUTCOMES



Fewer infections and use of antibacterial for systemic use[7]

Fewer ear infections and use of anti-infectives[3,8]

Fewer infections requiring hospitalisation[10]

Syneo will help transform the dietary management of Cow's Milk Protein Allergy, strengthening the immune system via modulation of the gut microbiota.[9,10]

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