

Investigating the management of allergy with amino acid-based formula and synbiotics in Australian infants with cow's milk allergy

ACTRN12624000670572

Status	RECRUITING
Sponsor	Western Sydney University
Enrollment	89 participants

Plain Language Summary

Cow's milk allergy (CMA) is one of the most common food allergies in infants, causing symptoms like rashes, vomiting, diarrhoea, and irritability. When breastfeeding is not possible, infants with CMA need a special formula that their body can tolerate. This study from Western Sydney University is following infants who are prescribed a specific amino acid formula that also contains a combination of prebiotics, probiotics, and a human milk sugar called 2'Fucosyllactose.

The aim is to gather real-world Australian evidence on how well this formula controls allergy symptoms, and to understand how it affects the baby's gut microbiome (the community of bacteria in the gut). Parents will complete questionnaires about their baby's symptoms, and microbiota samples will be collected at study visits.

Your infant may be eligible if they are under 6 months old, have recently been diagnosed (or are highly suspected) to have cow's milk allergy, are already formula-fed or you have decided to start formula feeding. Infants with purely functional gut symptoms (without suspected allergy) or who have contraindications to synbiotics — such as prematurity, short bowel, or cancer treatment — are not eligible.

Key Eligibility Criteria

Inclusion (4)

- Infants less than 6 months of age at study entry;
- With recently confirmed (or highly suspected) CMA, based on physician judgement;
- Already formula-fed or parents already made the decision to start with formula feeding;
- Written informed consent provided by parents/guardians, according to local law.

Exclusion (3)

- Infants with functional gastrointestinal symptoms where atopy and food allergy is NOT suspected.
- Contraindications to use synbiotics (e.g. prematurity, short bowel, parenteral nutrition, post pyloric feeding, central venous catheter, patients undergoing oncology treatment, graft-versus-host-disease, GVHD);
- Any other criteria, assessed by the physician, to contraindicate the use of an amino acid-based formula.

Locations (1 total)

NSW,SA, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624000670572>

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