

# SMASH: Study to Evaluate the Clinical Efficacy of an Extensively Hydrolysed Infant Formula With Synbiotics and a Human Milk Oligosaccharide (HMO) in Infants With Cow's Milk Protein Allergy (CMPA)

NCT07342621

---

Status	RECRUITING
Sponsor	Outcomes'10
Enrollment	41 participants

## Key Eligibility Criteria

---

### Inclusion (5)

- Infants under 10 months of age at study start (Visit 1).
- Suspected or recently confirmed cow's milk protein allergy (CMPA), as determined by the investigator.
- Already formula-fed, or parents/legal guardians have decided to initiate formula feeding.
- Inclusion in the study coincides with the first prescription of a hypoallergenic formula.
- Written informed consent obtained from parents or legal guardians in accordance with local regulations.

### Exclusion (7)

- Infants with functional gastrointestinal symptoms in whom atopy or food allergy is not suspected.
- Infants who have previously used an extensively hydrolyzed formula (EHF), an amino acid-based formula (AAF), a rice hydrolysate formula, or a soy-based formula.
- Infants who have previously used a partially hydrolyzed formula for the prevention of cow's milk protein allergy (CMPA).
- Infants for whom an amino acid-based formula (AAF) is more appropriate as first-line management, including severe forms of CMPA.
- Contraindications to the use of synbiotics (e.g., preterm infants <40 weeks of corrected gestational age at study start, immunodeficiency, short bowel syndrome, parenteral nutrition, post-pyloric feeding, central venous catheter, oncology treatment, or graft-versus-host disease).

... and 2 more (see full listing online)

## Locations (13 total)

---

Quironsalud Valencia Hospital, Valencia, Valencia, Spain  
Trinitat Health centre, Valencia, Valencia, Spain  
Malva-rosa Health centre, Valencia, Valencia, Spain  
... and 10 more locations