

Effects of Staged Adapted Inclusions in Infant Cereals on Oral-motors Patterns of 6-24 Month-old Children

NCT07318506

Status	RECRUITING
Phase	Not Applicable
Sponsor	Société des Produits Nestlé (SPN)
Enrollment	153 participants

Key Eligibility Criteria

Inclusion (11)

- Children between 6 months (182 days) to 24 months (730 days) of age (from enrollment to last visit):
- \[182-242\]-days of age from V1 to last visit for the 6-8-month-old age group 1.2. \[243-364\]-days of age from V1 to last visit for the 8-12-month-old age group 1.3. \[365-547\]-days of age from V1 to last visit for the 12-18-month-old age group 1.4. \[548-730\]-days of age from V1 to last visit for the 18-24-month-old age group
- Singleton, full-term infants (e 37 completed weeks of gestation), with a birth weight of e 2.5 kg and d 4.5 kg.
- Healthy children based on medical history as reported by parent(s) / LAR(s).
- Sit upright with or without support (such as, sitting with back against a chair or while being held) as reported by parent(s) / LAR(s)
- ... and 6 more (see full listing online)

Exclusion (7)

- \. Infant's parents or LARs have not reached legal age of majority (18 years) 2. Children with history of oral/facial malformations or surgery (i.e. cleft lip, cleft palate, tongue-tie/ankyloglossia), or history of tube feeding for any reason.
- \. Children with any chronic illness, congenital malformations (e.g., esophageal or intestinal atresia), surgical sequela (e.g., short bowel syndrome), gastroesophageal reflux disease, behavioral disorders, neurodevelopmental delay or illness that impacts feeding. \[children with an acute illness, such as a cold, gastroenteritis etc. can be included but can only attend the visits once they have recovered\].
- \. Children with feeding or swallowing difficulties/disorders, history of choking, or at high risk of choking.
- \. Child or sibling(s) who has known or suspected food allergy or intolerance, such as cows' milk protein allergy, celiac disease, lactose intolerance, soy allergy, fish allergy, or any other suspected or confirmed food allergies or intolerance.
- \. Children with undernutrition as determined by age-group weight threshold (based on parental reports): weight at \[6-8\]month < 6 kg; weight at \[8-12\]months: < 6.5 kg; weight at \[12-18\]months: < 7.5 kg; weight at \[18-24\] months: < 8.5 kg.
- ... and 2 more (see full listing online)

Locations (2 total)

Instituto DYM S.A., Barcelona, Spain
Institute of Agrochemistry & Food Technology CSIC, Valencia, Spain