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Effects of an infant formula containing hydrolysed protein on growth, tolerance and safety in healthy term infants

Submission date	Recruitment status	[X] Prospectively registered
06/07/2026	Not yet recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
08/07/2026	Ongoing	[_] Results
Last Edited	Condition category	[_] Individual participant data
08/07/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
In Europe, any infant formula made with hydrolysed proteins (proteins that have been broken down into smaller pieces) must be proven safe and appropriate through a clinical study before it can be sold, according to the European Food Safety Authority. The primary purpose of this study is to find out whether babies grow at the same rate when fed with a hydrolysed formula compared with a regular formula that contains whole milk protein. The study also looks at whether the formula made with hydrolysed proteins is safe for babies and how it affects common stomach and digestion problems.

Who can participate?
Healthy full-term infants aged up to 28 days

What does the study involve?
Participating infants are randomly allocated to two groups to receive either infant formula with hydrolysed proteins or ordinary infant formula with intact proteins for 3 months. Growth and the health status of the infant are followed and data on gastrointestinal symptoms is collected.

What are the possible benefits and risks of participating?
The participating infant may or may not benefit from this study in terms of growth, development, and gastrointestinal symptoms. The study can provide relevant evidence for future interventions and research in this field. No compensation for participating in this study is provided, but study products will be made available at no charge. The participating infant will also receive health checks including growth assessments at no cost.
A new formula may cause short-term gastrointestinal disturbances. Possible adverse events will be closely monitored during the study.

Where is the study run from?
Comac Medical Ltd (Bulgaria)

When is the study starting and how long is it expected to run for?
September 2026 to January 2028

Who is funding the study?
Valio Ltd (Finland)

Who is the main contact?
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Study information

Scientific Title
Multicenter, randomised, controlled, double-blind equivalence study to investigate the safety and suitability of a partially hydrolysed, cow’s milk based infant formula compared to cow’s milk-based infant formula with intact protein

Acronym
NutriBaby

Study objectives
1. The primary objective is to evaluate the equivalence between the hydrolysed formula and the infant formula with intact protein with respect to daily weight gain.
2. The secondary objective is to investigate effects of the partially hydrolysed formula on growth and gastrointestinal symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Safety and suitability

Study type(s)

Health condition(s) or problem(s) studied
Safety and suitability of a partially hydrolysed, cow’s milk based infant formula

Interventions
This study is a multicenter, randomised, controlled, double-blind equivalence study including two study arms:
Arm 1 (test formula): partially hydrolysed, cow’s milk-based infant formula
Arm 2 (control formula): a cow’s milk-based infant formula with intact protein

Recruitment will be performed in five study sites in Bulgaria. Computer-generated randomisation lists are stratified by site and gender using random block sizes.

The study is conducted in healthy, full-term, exclusively formula-fed infants. The total duration of the intervention for each participant is 3 months (approximately 90 days).

Formulas are provided for free to the participating families in similar blank tins of 800 g powder. Formula consumption is ad libitum, but a feeding table instruction is provided with the parental information leaflet to guide and encourage the age-appropriate consumption of the supplied products. The study formulas are instructed to be used at every feeding.

Intervention Type
Other

Primary outcome(s)
1. Weight measured using electronic scales at baseline, 30, 60, 90 days

Key secondary outcome(s)
1. Length measured using an infantometer at baseline, 30, 60, 90 days

2. Head circumference measured using unelastic tape at baseline,30,60,90 days

3. BMI measured using weight divided by length squared at baseline, 30, 60, 90 days

4. Feeding tolerance and gastrointestinal-related behaviors measured using the Infant Gastrointestinal Symptom Questionnaire (IGSQ-13) at baseline, 30, 60, 90 days

5. Formula intake measured using a feeding diary at Days 1-14, 22-29, 52-59, 82-89

Completion date
31/01/2028

Eligibility

Key inclusion criteria
1. Gestational age 37+0 weeks – 42+0 weeks at birth
2. Birthweight between 2,500 and 4,500 g
3. Boys and girls
4. Healthy at birth and screening, e.g., major congenital anomalies, absence of serious illness requiring hospitalization, no metabolic or gastrointestinal conditions affecting growth or nutrition, stable vital signs.
5. Weight-for-age Z-score (WAZ), weight-for-length Z-score (WHZ), and length-for-age Z-score (LAZ) at screening within the normal range according to WHO Child Growth Standards (i.e., between –2 and 2)
6. Age at enrolment ≤28 days of age
7. Exclusively formula fed for at least 5 days prior to inclusion
8. Exclusively formula fed during the entire intervention period
9. Parents agreeing to initiate complementary feeding after finalization of the study
10. Written informed consent from parent(s) and/or legal guardian(s) aged ≥18 years

Healthy volunteers allowed
Yes

Age group
Neonate

Lower age limit
1 Days

Upper age limit
28 Days

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Severe acquired or congenital diseases, mental or physical disorders, including cow's milk protein allergy (CMPA), lactose intolerance and diagnosed medical conditions that are known to affect growth, including severe gastroesophageal reflux (throwing up or spitting up more than a teaspoon of milk >8 times daily
2. Incapability of parents to comply with the study protocol
3. Inability to complete study diaries or comply with study procedures
4. Participation in another clinical trial
5. Unwillingness to accept the formula supplied by the study as the only formula for their child during study participation
6. Infants fed a special diet other than standard, non-hydrolysed, cow's or goat's milk based infant formula

Date of first enrolment
01/09/2026

Date of final enrolment
31/10/2027

Locations

Countries of recruitment
Bulgaria

Sponsor information

Organisation
Comac Medical

Funder(s)

Funder type

Funder Name
Valio

Alternative Name(s)
Valio Ltd, Valio Oy

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Finland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date