ISRCTN18275142 https://doi.org/10.1186/ISRCTN18275142

Oral nutritional supplement to support weight and length gain in stunted children aged 12 to 18 months in Palembang, Indonesia

Submission date
15/05/2026

Recruitment status
No longer recruiting

Registration date
20/05/2026

Overall study status
Completed

Last Edited
18/05/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims:
Stunting is when a child is shorter than expected for their age because of long-term undernutrition. This study looks at whether a milk-based oral nutritional supplement (1 kcal/ml with a 13% protein-energy ratio and 0% sucrose) can help stunted young children gain length and weight over time. The study also looks at how well the product is tolerated, whether children can take it as planned, and how parents feel about the product.

Who can participate?
Children aged 12 to 18 months who have stunting, defined by a height-for-age Z-score between -2 and -3 standard deviations, can take part if their parent or legal guardian gives written consent. The child must be an outpatient and under pediatrician monitoring. Children with major medical conditions that may affect growth or feeding, tuberculosis, congenital heart disease, prematurity, cow's milk protein allergy, or lactose intolerance cannot take part.

What does the study involve?
Children receive an oral nutritional supplement providing 1 kcal/ml at a dose of two servings of 200 ml per day for up to 5 months. The study team follows the children monthly to measure length and weight, check gastrointestinal tolerance, monitor infections and safety, and ask about product acceptability and parent perception. Dietary assessment is done at baseline and month 5, and growth biomarkers are measured in a small subgroup of children.

What are the possible benefits and risks of participating?
The supplement is intended to support growth, but individual benefit cannot be guaranteed. Possible risks include stomach or bowel symptoms such as vomiting or diarrhea and minor discomfort from blood sampling at study visits. Any medical problems identified during the study are managed according to standard clinical care.

Where is the study run from?
Puskesmas Kota Palembang (Indonesia)

When is the study starting and how long is it expected to run for?
January 2025 to February 2026

Who is funding the study?
PT Nestlé Indonesia

Who is the main contact?
Dr Moretta Damayanti, moretta.d@fk.unsri.ac.id

Contact information

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Principal investigator, Scientific

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Additional identifiers

Study information

Scientific Title
Impact of an oral nutritional supplement on linear growth velocity in stunted children aged 12 to 18 months in Palembang City: a quasi-experimental single-arm study

Study objectives
To evaluate the effect of a high-energy-density oral nutritional supplement on growth outcomes in stunted children aged 12 to 18 months over a 5-month intervention period. The primary objective was to assess linear growth velocity (length velocity) compared with WHO reference standards.

Secondary objectives included evaluation of weight gain velocity, changes in height-for-age and weight-for-age Z-scores, gastrointestinal tolerance, incidence of common infections, product acceptability, parental perception, dietary diversity, and changes in growth biomarkers including insulin-like growth factor 1 and leptin in a sub-sample of participants.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/12/2024, Research Ethics Committee of RS Mohammad Hoesin Palembang (Jl. Jendral Sudirman KM 3,5, Sekip Jaya, Kecamatan Kemuning, Kota Palembang, Sumatera Selatan, Palembang, 30126, Indonesia; +62 (0711) 354088; kepk@fk.unsri.ac.id), ref: DP.04.03/D.XVIII. 06.08/ETIK/273/2024

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Stunting in children aged 12 to 18 months

Interventions
Participants receive a milk-based oral nutritional supplement (ONS) with an energy density of 1 kcal/ml, a protein-energy ratio (PER) of 13% and 0% sucrose. The product is administered as two

servings of 200 ml per day (approximately 400 kcal/day) for up to 5 months (maximum 150 days). This is a single-arm, open-label study with no placebo or comparator group, and no randomization is performed. Participants are followed monthly for anthropometry, gastrointestinal tolerance, infection monitoring, product acceptability, parental perception, and safety assessments; a dietary assessment is performed at baseline and Month 5, and growth biomarkers are measured in a sub-sample of participants.

Intervention Type
Supplement

Primary outcome(s)
1. Length velocity: recumbent length measured using anthropometry (calculated as mm/month) at baseline (Visit 0) to month 5 (visit 5)

Key secondary outcome(s))
1. Weight velocity measured using body weight anthropometry (calculated as g/month) at baseline (visit 0) to month 5 (visit 5)

2. Height-for-age Z-score (HAZ) measured using WHO Child Growth Standards at baseline (Visit 0) to month 5 (visit 5)

3. Weight-for-age Z-score (WAZ) measured using WHO Child Growth Standards at baseline (visit 0) to month 5 (visit 5)

4. Gastrointestinal tolerance measured using the Infant Gastrointestinal Symptom Questionnaire (IGSQ) and 3-day stool diary at month 1 to month 5

5. Incidence of common infections measured using physician assessment and clinical monitoring of infection events at month 1 to month 5

6. Product acceptability measured using ability to consume the recommended daily serving of investigational product at month 1 to month 5

7. Parental perception of product quality and value measured using structured questionnaire responses at month 1 to month 5

8. Dietary diversity (minimum dietary diversity [MDD]) measured using 24-hour dietary recall based on WHO/UNICEF Infant and Young Child Feeding (IYCF) guidelines at baseline and month 5

9. Growth biomarkers measured using serum insulin-like growth factor-1 (IGF-1) and leptin measurement in a sub-sample of participants (n = 20) at baseline and month 5

Completion date
02/02/2026

Eligibility

Key inclusion criteria
1. Children aged 12 to 18 months at the time of enrollment
2. Stunted children, defined as height-for-age Z-score (HAZ) between <2 and ≥-3 SD according to WHO growth standards

3. Parent(s)/legal guardian(s) willing to provide written informed consent and to allow participation for up to 6 months
4. Willingness to comply with study product administration as prescribed by a pediatrician
5. Ability and willingness to comply with all study procedures and protocol requirements
6. Managed as outpatients and under regular monitoring by pediatrician

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 months

Upper age limit
18 months

Sex
All

Total final enrolment
74

Key exclusion criteria
1. Children with short stature not classified as stunting (≥-2 SD)
2. Presence of chronic or major medical conditions that may affect growth or feeding, including but not limited to: tuberculosis, prematurity, small for gestational age (SGA), congenital heart disease, or other significant acute/chronic illnesses
3. Requirement for hospitalisation at the time of screening or during enrolment
4. History of cow's milk protein allergy (CMPA) or lactose intolerance

Date of first enrolment
02/01/2025

Date of final enrolment
23/12/2025

Locations

Countries of recruitment
Indonesia

Sponsor information

Organisation
Nestlé (Indonesia)

Funder(s)

Funder type

Funder Name
Nestlé

Alternative Name(s)
Nestlé S.A.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available