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Human milk or preterm formula after hospital discharge in infants born at 32-34 weeks: effects on growth, nutritional status, and feeding tolerance

Submission date
10/11/2026

Recruitment status
No longer recruiting

Registration date
13/11/2026

Overall study status
Completed

Last Edited
13/11/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

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Medical and Health Project of the Science
PKJ2023-Y59

Technology Development Fund of Pudong New Area for Public Welfare Research
PKJ2024-Y09

Study information

Scientific Title
Post-discharge human milk or preterm formula in infants born at 32⁰-34⁶ weeks: growth, micronutrient status and feeding tolerance in routine care

Study objectives
1. To compare weight gain velocity from hospital discharge to 4 months postmenstrual age between the two groups (primary outcome)
2. To compare length gain velocity, head circumference gain velocity, z-scores for weight/length /head circumference, and the proportion of catch-up growth (Δz ≥ 0.67), hemoglobin, serum ferritin, 25-hydroxyvitamin D levels, the detection rates of anemia, iron deficiency and vitamin D insufficiency, as well as feeding tolerance (secondary outcomes)
3. To describe the actual utilization rate of human milk fortifier
4. To provide local evidence for the development of individualized post-discharge feeding and follow-up management pathways for moderate-late preterm infants

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/12/2022, Medical Ethics Committee of Shanghai First Maternity and Infant Hospital (2699 Gaoke West Road, Pudong New Area, Shanghai, 201204, China; +86 021-20261000; kjk@51mch.com), ref: 53

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Post-discharge human milk or preterm formula in healthy late moderate preterm infants

Interventions
Post-discharge nutrition of late and moderately preterm infants is poorly evidenced, and feeding mode may shape catch-up growth and micronutrient status. This study compares growth, micronutrient status and feeding tolerance in infants born at 32⁰–34⁶ weeks' gestation (moderate-to-late preterm; M/LPT) fed human milk or post-discharge preterm formula to 4 months' corrected gestational age (CGA), and documents fortifier use in routine care.

In this single-centre, non-randomised, open-label cohort, healthy M/LPT infants were enrolled and analysed: human milk (≥ 75% of intake) or post-discharge preterm formula , to 4 months' CGA. The primary outcome was weight growth velocity; length and head-circumference velocity, haemoglobin (Hb), serum ferritin, 25-hydroxyvitamin D (25OHD) and tolerance were secondary; velocities were adjusted for gestational age and birth weight (ANCOVA; sex as sensitivity analysis).

Intervention Type
Other

Primary outcome(s)
1. Weight gain velocity, calculated by serial weight records measured using standard WHO calibrated weighing scales at discharge and 4 months of corrected gestational age

Key secondary outcome(s)
1. Length and head circumference growth velocity, calculated by serial length and head circumference records measured using standard WHO measuring tape at discharge and 4 months of corrected gestational age

2. Weight/length/head circumference-for-age z-scores and catch-up growth proportion ($\Delta z \geq 0.67$), measured using the WHO Child Growth Standards at 4 months of corrected gestational age

3. Levels of hemoglobin, serum ferritin, 25-hydroxyvitamin D measured using clinical laboratory biochemical tests at 4 months of corrected gestational age

4. Feeding tolerance from discharge to 4 months of corrected gestational age, measured using clinical feeding records (including vomiting, abdominal distension, feeding interruption), accessed at the end of the study

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. "Healthy" late moderate preterm infants with a gestational age of 32+0 to 34+6 weeks (determined by last menstrual period or first-trimester ultrasound) at a postmenstrual age of 2 weeks (about 2 weeks after birth)
2. Clinically stable
3. Can tolerate full enteral feeding

Healthy volunteers allowed
Yes

Age group
Neonate

Lower age limit
7 Days

Upper age limit
2 Weeks

Sex
All

Total final enrolment

Key exclusion criteria
1. Congenital malformations (including but not limited to gastrointestinal malformations, congenital heart disease, chromosomal abnormalities, etc.)
2. Diseases affecting growth, including severe bronchopulmonary dysplasia (requiring inspired oxygen concentration >30% or continuous positive airway pressure beyond a postmenstrual age of 36 weeks), metabolic disorders (e.g., congenital hypothyroidism, phenylketonuria, etc.), severe cardiac or renal diseases, necrotizing enterocolitis with extensive bowel resection, grade IV intraventricular hemorrhage
4. Use of medications that may affect food digestion, absorption or sleep (e.g., sedatives, glucocorticoids, etc.)
5. Infants whose parents refuse participation or are unable to complete follow-up

Date of first enrolment
01/01/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
China

Study participating centre
Shanghai First Maternity and Infant Hospital
2699 Gaoke West Road, Pudong New Area, Shanghai , China
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Sponsor information

Organisation
Shanghai First Maternity and Infant Hospital

ROR
https://ror.org/05myyzn85

Funder(s)

Funder type

Funder Name
Technology Development Fund of Pudong New Area for Public Welfare Research

Funder Name
Medical and Health Project of the Science

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available