

# A clinical trial to investigate the promotion of child health by Bifidobacterium infantis YLGB-1496

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| <b>Submission date</b><br>19/07/2024   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>22/07/2024 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>16/07/2025       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Bacteria colonize the intestine early in life, which helps to establish the human intestinal mucosal barrier, promote the maturation of immune function, and prevent infection by intestinal pathogens. The stability of the intestinal microecology is of great significance for immune defence against pathogenic microorganisms and the metabolism of nutrients. Bifidobacteria play a crucial balancing role in the intestinal microecology and actively promote the growth and development of infants and young children. The safety and effectiveness of the infant bifidobacterium YLGB-1496 strain, which is a marketed product, has been widely demonstrated, but there is still a lack of direct evidence on the impact of infant bifidobacterium YLGB-1496 on the health of infants and young children. This study aims to evaluate the intervention of human milk-derived infant bifidobacterium YLGB-1496 in promoting the growth and development of healthy infants and young children of different ages, as well as improving allergic, respiratory and gastrointestinal diseases.

### Who can participate?

Healthy infants aged 0-3 years old

### What does the study involve?

Participating infants are randomly allocated to be supplemented with probiotics or placebo (maltodextrin) for 3 months, and the researchers observe the incidence of allergies, the health status of the infant's intestinal tract (functional gastrointestinal diseases such as diarrhea and constipation, as well as functional dyspepsia syndrome), the incidence of upper respiratory tract infections (including the number of episodes, duration, intensity, and medication treatment), and the changes in diversity and abundance of intestinal flora during the supplementation period.

### What are the possible benefits and risks of participating?

Participation in this study may or may not promote the growth and development of young children, optimize the composition of intestinal flora, improve immune function, reduce the risk of common infectious diseases and allergic diseases, and improve quality of life. The

examination of the child's stool specimen can help to understand the characteristics of the baby's intestinal flora, provide relevant evidence for future individualized nutritional interventions, and provide useful information for research in this field. The child will not receive any compensation for participating in this study. To compensate for the inconvenience the child may face due to participating in this study, the study will cover the cost of stool tests conducted during the study period and follow-up visits, and provide research products at no cost.

Where is the study run from?

Baoxing County Center for Disease Control and Prevention (China)

When is the study starting and how long is it expected to run for?

January 2024 to September 2025

Who is funding the study?

National Center of Technology Innovation for Dairy Funding (China)

Who is the main contact?

Dr Ke Chen, kechen@uestc.edu.cn

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Ke Chen

### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

# Study information

## Scientific Title

A prospective, multi-center, placebo-controlled, randomized, double-blind, parallel-group clinical trial to investigate the promotion of child health by Bifidobacterium infantis YLGB-1496

## Study objectives

To evaluate the effect of infant Bifidobacterium YLGB-1496 intervention on promoting growth and development (including intestinal flora and growth) and improving the incidence of allergic diseases, respiratory and gastrointestinal diseases in healthy infants of different ages, and to analyze the safety and correlation between infant Bifidobacterium YLGB-1496 and growth and development, allergy incidence, and intestinal flora of infants.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 24/06/2024, Ethics Committee of Baoxing County Center for Disease Control and Prevention (No.1 Zhongling Avenue, Baoxing County, Ya'an, 625799, China; +86 (0)835 682 2027; 263662086@qq.com), ref: 2024(01)

## Study design

Prospective multi-center placebo-controlled randomized double-blind parallel-group clinical trial

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Allergic disease in children

## Interventions

A public health epidemic professional who is not directly involved in the execution of the study will use the RAND function in Excel to generate random numbers. Children who meet the inclusion criteria will be coded by the random numbers and assigned into the two groups based on the sequence of the random numbers.

### Intervention Group:

Once a day, 1 packet (containing Bifidobacterium infantile YLGB-1496 strain  $1.5 \times 10^{10}$  CFU/ packet), the course of treatment starts from the day of use of probiotic products, and continues for 3 months.

### Control Group:

One package (maltodextrin, without infantile bifidobacterium YLGB-1496) was given once a day, starting on the day of the placebo product and ending with continuous supplementation for 3 months.

## Intervention Type

## Supplement

### Primary outcome(s)

Incidence of allergy in children measured using data from hospital medical documents and records during the whole study course (total of 3 months)

### Key secondary outcome(s)

1. Intestinal health status of infants (incidence of functional gastrointestinal diseases such as diarrhea and constipation and functional dyspepsia syndrome), measured using data from hospital medical documents and records during the whole study course (total of 3 months)
2. Incidence of upper respiratory tract infections in infants and young children (including frequency, duration, intensity, and medication), measured using data from hospital medical documents and records during the whole study course (total of 3 months)
3. Changes in the diversity and abundance of intestinal flora. Fecal samples will be collected to test the gut microbiome based on 16S rDNA information. Shannon, Simpson, Chao1, and ACE indices will be used as indicators of the alpha diversity. Principal coordinate analysis (PCoA), based on the Bray-Curtis distance, will be used to analyze the  $\beta$ -diversity. LDA scores ( $>4.0$ ) derived from the LEfSe analysis at genus and species levels will be used to identify several bacterial genera and species that differed in the two groups. Timepoints: before and after intervention
4. Growth and development of children: weight, length and head circumference of children measured before and after the intervention

### Completion date

01/09/2025

## Eligibility

### Key inclusion criteria

1. Healthy infants born at 37 to 42 weeks of gestation were artificially fed and had a birth weight greater than or equal to 2500 and less than 4000 g, without sex restriction
2. The infant's mother has no diagnosed metabolic diseases such as diabetes, hepatitis B, HIV and other infectious diseases
3. Three age groups were included: 0~6 months old, 7~12 months old and 13~36 months old
4. The child's parent or primary guardian consents to the collection of faecal samples during the study period;
5. No clinically diagnosed allergic diseases at the time of enrollment (including but not limited to eczema, asthma, allergic proctocolitis, allergic rhinitis, hay fever, etc)
6. Register in the child care department of the local maternal and child health hospital and receive regular physical examinations and feeding advice and guidance from the child health doctor
7. The family or primary guardian commits not to add additional probiotic products (including formula containing probiotics) to the infant during the intervention period
8. The guardian of enrolled subjects agrees to participate in the intervention study and signs a written informed consent, and can understand and fill in the infant diary and other forms as required

### Participant type(s)

Healthy volunteer, Resident

### Healthy volunteers allowed

No

**Age group**

Child

**Lower age limit**

0 years

**Upper age limit**

3 years

**Sex**

All

**Total final enrolment**

100

**Key exclusion criteria**

1. The infant has a history of birth asphyxia or NICU hospitalization
2. The child has a birth defect or congenital abnormality
3. The mothers of infants and young children have pregnancy-induced hypertension syndrome, eclampsia and preeclampsia, gestational diabetes, gestational cholestasis and other obstetric risk factors, and history of alcoholism and drug abuse
4. The infants had used antibiotics within 2 weeks before enrollment
5. Diseases that definitely affect the growth and development of infants (such as pneumonia, severe diarrhea, severe constipation, severe milk protein allergy, malnutrition, gastrointestinal surgery, etc., neurological diseases such as severe congenital heart disease, epilepsy, cerebral palsy, mental retardation, and exact inherited metabolic diseases, chromosomal diseases, genetic diseases, etc) 1 month before enrollment
6. Complicated with serious primary diseases of other vital organs or systems such as heart, liver, kidney and hematopoietic system;
7. Prior to screening, use of experimental drugs after birth, participation in other clinical studies
8. The probiotic products or formula containing bifidobacterium infantilum YLGB-1496 were taken one month before enrollment (for infants <1 month old, calculated from birth to enrollment)
9. Infants who had used immunosuppressive drugs (such as glucocorticoids and immunosuppressants) before enrollment
10. Infants and young children allergic to known probiotic product ingredients
11. Malnourished children requiring hospitalization
12. Other reasons that the investigator deems inappropriate to participate in the clinical trial, such as influencing efficacy evaluation or poor adherence

**Date of first enrolment**

01/08/2024

**Date of final enrolment**

01/03/2025

**Locations**

## **Countries of recruitment**

China

## **Study participating centre**

**Baoxing County Center for Disease Control and Prevention**

No.1 Zhongling Avenue

Baoxing County

Ya'an

China

625799

## **Study participating centre**

**Xindu Maternal and Children's Health Care Hospital**

No. 309 Xindu Avenue

Xindu District

Chengdu

China

610599

## **Sponsor information**

### **Organisation**

Baoxing County Center for Disease Control and Prevention

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

National Center of Technology Innovation for Dairy Funding

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

The datasets generated and/or analyzed during the current study will be published as a supplement to the results publication.

# IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |                               | 01/07/2025   | 16/07/2025 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |