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

Submission date
19/07/2024

Recruitment status
No longer recruiting

Registration date
22/07/2024

Overall study status
Ongoing

Last Edited
16/07/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
https://orcid.org/0000-0001-7455-0900

Contact details
1617 Riyue Avenue
Qingyang District
Chengdu
China
610091
+86 (0)13981782973
kechen@uestc.edu.cn

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 1.5×10^10 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 measure
Incidence of allergy in children measured using data from hospital medical documents and records during the whole study course (total of 3 months)

Secondary outcome measures
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 β-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

Overall study start date
15/01/2024

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

Age group
Child

Lower age limit
0 Years

Upper age limit
3 Years

Sex
Both

Target number of participants
100

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

Sponsor details
No.1 Zhongling Avenue
Baoxing County
Ya'an
China

625799
+86 (0)8356822027
263662086@qq.com

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research organisation

Funder Name
National Center of Technology Innovation for Dairy Funding

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/01/2026

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?
Results article		01/07/2025	16/07/2025	Yes	No