ISRCTN33436648 https://doi.org/10.1186/ISRCTN33436648

The study aims to investigate the effect of the level of probiotic K12 content on enhancing children's immunity and reducing the frequency of their occurrence of diseases such as pharyngitis, tonsillitis, and rhinitis

Submission date 02/03/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/05/2026	**Overall study status** Completed	
Last Edited 01/09/2026	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific, Public, Principal investigator

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Study information

Scientific Title

The safety and efficacy of Streptococcus salivarius subspecies thermophilus K12 in improving recurrent respiratory tract infections in children: a randomized, double-blind, placebo-controlled trial

Study objectives
To evaluate the safety and effectiveness of K12 in children to improve the symptoms of ear, nose and throat (ENT)/upper respiratory tract infections (URTIs).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/01/2026, Ethics Review Committee of Baoxing Center for Disease Control and Prevention (No. 1, Zhongling Avenue, Baosheng County, Anya City, Sichuan Province, Zhongling, 625700, China; +86 (0)835-6822027; 263662086@qq.com), ref: Research Ethics Review 2026 (01)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Recurrent respiratory tract infections in children

Interventions
Current interventions as of 30/06/2026:

Participants were randomised using SPSS to either a low dose of probiotic bacteria (100 million CFP), a high dose of probiotic bacteria (5 billion CFP) or a placebo tablet one time per day (sterile powder, same derivative). The intervention period was 12 weeks, and saliva was taken after the intervention, after 6 weeks of intervention and at the end of the intervention, and the sample inspection was carried out during the 13 weeks of follow-up. At Week 0, Week 3, Week 6, Week 9, Week 12 and Week 16, questionnaires were completed and during the intervention the patients were asked to take the corresponding product every day and record adverse reactions and compliance. During the study, the doctor recorded the incidence of upper respiratory tract

infections, including the number of attacks, symptoms, and duration. By analyzing the statistics and analysis of these data, the improvement of the recurrence rate of the upper respiratory tract infection was calculated. In addition, the Canadian Acute Respiratory and Flu Scale (CARIFs) was used to quantify the incidence of upper respiratory infections in participants.

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Previous interventions as of 29/06/2026:

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Intervention Type
Supplement

Primary outcome(s)
1. Upper respiratory tract infections measured using the number of episodes, symptom manifestations, duration and the Canadian Acute Respiratory Illness and Flu Scale (CARIFs), at Week 0, Week 3, Week 6, Week 9, Week 12 and Week 16

Key secondary outcome(s)

Completion date
30/08/2026

Eligibility

Key inclusion criteria
1. Consistent with the diagnostic criteria for the clinical and clinical treatment of recurrent respiratory tract infection (2022)
2. Aged 3 to 18 years old
3. During the study (screening to follow-up), no probiotics, probiotics and cogenic milk products were used in this study
4. Agree to sample saliva and other biological samples during this study
5. The guardian of the child is aware of the study and signed the informed consent form

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
3 Years

Upper age limit
18 Years

Sex
All

Total final enrolment
179

Key exclusion criteria
1. In the first month of the group, the children of the same strain were studied
2. Treatments such as antibiotics, disinfectants, antifungal drugs, glucocorticosteroids and other treatments were accepted within 7 days of entering the group
3. Children who need hospitalization for malnutrition
4. Known to be sensitive, intolerant or allergic to any research product (including lactose, milk protein, etc)
5. Use any experimental drugs for the first 3 months of screening and participate in other clinical studies
6. Diagnosis of basic disease, such as above-moderate anemia, ricular disease, chronic diarrhea, stable diseases, congenital cardiovascular malformity, various causes of severe malnutrition, secondary immunodeficiency, kidney disease, cerebral palsy, and long-term immune inhibitors
7. Congenital immunodeficiency diseases (such as the common immunodeficiency disease in China): the X chain does not have hepatitis C, X chain high immunoglobulinemia, eczema, necrosis, or thrombocytopenia immunodeficiency syndrome
8. In the first 3 months of the group, took drugs that affected immune function (immunosuppressant, immunoenhancers, hormones, blood products, Chinese medicine, etc)
9. The researchers judge that there is a discomfort involved in compliance or safety
10. Vaccination or other active vaccines in the first 4 weeks of screening

Date of first enrolment

13/03/2026

Date of final enrolment
15/05/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
Baoxing Center for Disease Control and Prevention

Funder(s)

Funder type

Funder Name
Wecare Probiotics (Suzhou) Co., Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be stored in a publicly available repository, the Clinical Trial Management Public platform (http://www.medresman.org.cn/login.aspx). Upload original data within 6 months after the end of the trial.

IPD sharing plan summary
Stored in publicly available repository