

# Efficacy and safety of a probiotic supplement containing *L. plantarum* and *P. acidilactici* strains in young children with common respiratory viral infections

<b>Submission date</b> 04/10/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/10/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/01/2026	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Uncomplicated upper respiratory infections are common in children and typically caused by viruses. Previous studies have shown intake of some probiotics can reduce the duration of such respiratory infections in children, when taken in a preventive manner. The aim of this study is to determine if a particular probiotic formula can reduce the duration of symptoms when taken after the onset of such respiratory infections in children.

### Who can participate?

Infants and children, 6 months to 5 years old, with an upper respiratory infection with fever and throat pain (pharyngitis), whose symptoms are of likely viral origin, as per doctor's judgment.

### What does the study involve?

Eligible children are randomly allocated to receive either the specific probiotic formula (containing strains *L. plantarum* KABP033, KABP023 and KABP022 and *P. acidilactici* KABP021) in capsules, or identically-looking placebo capsules, twice daily. Study subjects can also receive standard of care treatment, at study investigators discretion, consisting of ibuprofen (an approved anti-inflammatory drug) and/or cetirizine (an approved anti-histaminic drug).

Parents or caregivers are taught to rate their children's pain using a visual scale (the FLACC scale). Parents or caregivers are instructed to fill a daily diary with the observed FLACC score, as well as the highest body temperature, presence of runny nose (rhinorrhea), nasal congestion, cough, use of ibuprofen and use of cetirizine.

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

The probiotic strains used in this study were previously found to be safe, as well as effective at shortening the duration of fever and respiratory symptoms in a clinical trial in 300 Covid19 patients. Therefore, children who participate in this study could have the duration of the symptoms of their upper respiratory infection shortened. And if an adverse health event

occured related to the participation in the study, the participants can reach the investigators anytime (24h availability by phone every day), and costs would be covered by an insurance already contracted by the study funder.

Where is the study run from?

Medica Sur Hospital, in Mexico City. (Mexico)

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

May 2023 to September 2024

Who is funding the study?

AB-BIOTICS SA (part of KANEKA Corporation) (Spain)

Who is the main contact?

Dr Diana Maria Andrade Platas, dianamandrade@yahoo.com

## Contact information

### Type(s)

Principal investigator

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**Additional identifiers****Protocol serial number**

RESPIKIDS-II

**Study information****Scientific Title**

Efficacy and safety of *L. plantarum* KABP033, KABP023 and KABP022 and *P. acidilactici* KABP021 in upper respiratory tract infections of viral origin in children aged 6 months to 5 years

**Study objectives**

The combination of probiotic strains *L. plantarum* KABP033, KABP023 and KABP022 and *P. acidilactici* KABP021, when taken twice daily, would reduce the duration of symptoms of upper respiratory tract infections of viral origin, compared to placebo.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 22/09/2023, Committee for Ethics and Research in Studies in Humans (Comité de Ética e Investigación para Estudios en Humanos (CEIEH)), Medica Sur Hospital (Puente de Piedra No. 150 Colonia Toriello Guerra, Tlalpan, Mexico City, 14050, Mexico; +52 55 5424 7200; comiteinvestigacion@medicasur.org.mx), ref: CB148-CEI153

**Study design**

Randomized double-blind placebo-controlled parallel-group study

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Upper respiratory tract infections with pharyngitis, of likely viral origin, in children 6 months to 5 years old

## **Interventions**

Using a centralised computer-based randomisation list, patients are randomised 1:1 to receive either probiotic capsules or indistinguishable-looking placebo capsules, to be taken orally twice daily for 15 days (days 1 to 15 of the study). Randomisation list will be prepared by personnel not directly participating in the study and kept in a sealed envelope until study completion.

Probiotic capsules contain *Lactiplantibacillus plantarum* strains KABP033, KABP023 and KABP022 and *Pediococcus acidilactici* strain KABP021, totaling 2 billion CFUs (colony-forming units) in a dextrin carrier. Placebo capsules contain dextrin carrier only. All capsules are made of hydroxymethyl-propyl-cellulose (HPMC) and are delivered in anonymous blisters, inside of anonymous boxes (30 capsules per box).

Study subjects can also receive pediatric standard of care treatment, at study investigators discretion, consisting of ibuprofen suspension as anti-inflammatory drug (10mg per Kg of body weight per day) and/or cetirizine suspension as anti-histaminic drug (0.25mg per Kg of body weight per day). Finally, should study subjects develop infectious symptoms of likely bacterial origin after the study initiation, study investigators can prescribe antibiotic rescue medication at standard pediatric doses, consisting of amoxicillin clavulanate suspension (at 45mg per Kg of body weight per day), or clarythromycin suspension (at 7.5 mg per Kg of body weight per day) if there is a history of allergy to penicillins.

## **Intervention Type**

Supplement

## **Primary outcome(s)**

Number of days with fever (body temperature  $>37.5^{\circ}\text{C}$ ), as measured with a thermometer, and number of days with pain score  $>3$ , as measured with the FLACC score ("Face, Legs, Activity, Cry and Consolability"; Merkel et al. *Pediatric Nursing* 1997, 23:293-297), both recorded daily by parents in a diary from day 1 to 15 of intervention.

## **Key secondary outcome(s)**

1. Area under the curve (AUC) of the FLACC score ("Face, Legs, Activity, Cry and Consolability"; Merkel et al. *Pediatric Nursing* 1997, 23:293-297), as recorded daily by parents in a diary from day 1 to 15 of intervention.
2. Area under the curve (AUC) of body temperature (in Celsius degrees), as recorded daily by parents in a diary from day 1 to 15 of intervention.
3. Etiological agent (using multiplex PCR for 16 respiratory viruses), as determined on nasopharyngeal swabs taken on day 0.
4. Metabolome analysis (polar and semi-polar metabolites, as analysed by HPLC-MS) of salivary samples taken on days 1 and 15.
5. Concentration of immunoglobulin A (IgA), TNF-alpha and interleukins 1b, 4, 6, 10, 17 and 18 in salivary samples taken on days 1 and 15.
6. Number of days with cough, as recorded daily by parents in a diary from day 1 to 15 of intervention.
7. Number of days with nasal congestion, as recorded daily by parents in a diary from day 1 to 15 of intervention.
8. Number of days with rhinorrhea, as recorded daily by parents in a diary from day 1 to 15 of intervention.

9. Number of days of intake of NSAIDs (ibuprofen), as recorded daily by parents in a diary from day 1 to 15 of intervention.
10. Number of days of intake of antihistaminics (cetirizine), as recorded daily by parents in a diary from day 1 to 15 of intervention.
11. Number of days of intake of antibiotics rescue medication, as recorded daily by parents in a diary from day 1 to 15 of intervention.
12. Number of medical or emergency visits, as recorded daily by parents in a diary from day 1 to 15 of intervention.
13. Number of medical or emergency visits after day 15, as recorded during face-to-face visits on days 30 and 60.
14. Number of different symptoms (of FLACC>3, fever >37.5°C, presence of cough, rhinorrhea and nasal congestion), as recorded daily by parents in a diary from day 1 to 15 of intervention.
15. Number of different symptoms (of FLACC>3, fever >37.5°C, presence of cough, rhinorrhea and nasal congestion), as recorded during face-to-face visits on days 30 and 60.

**Completion date**

20/09/2024

## Eligibility

**Key inclusion criteria**

1. Infants and children, 6 months to 5 years old, with upper respiratory infection of likely viral origin (based on investigator's judgment of symptoms) with pharyngitis.
2. Having a FLACC score ("Face, Legs, Activity, Cry and Consolability"; Merkel et al. Pediatric Nursing 1997, 23:293-297) > 3 and body temperature >37.5°C.
3. Symptoms started within 48h of entry visit.
4. Written informed consent provided by parents or caregivers.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 months

**Upper age limit**

5 years

**Sex**

All

**Total final enrolment**

75

**Key exclusion criteria**

1. Tonsillitis, cervical lymphadenitis, otitis media or scarlatiniform rash (symptoms suggestive of bacterial infection).
2. Preterm infants or those having been born weighting <2500gr.
3. Failure to thrive
4. Use of antibiotics, antivirals or probiotics for more than 48h within 2 weeks of study entry.
5. Breastfed children whose mothers have taken antibiotics, antivirals or probiotics for more than 48h within 2 weeks of study entry.
6. History of two or more invasive infections (meningitis, osteomyelitis, sepsis).
7. History of recurrent, severe respiratory infections within 12 months of study entry
8. Chronic diarrhea or gastroesophageic reflux disease (GERD).
9. Congenital heart, respiratory or digestive disease.
10. Primary or secondary immunodeficiency.
11. Asthma.
12. Any other condition that, according to the judgment of the principal investigator, warrants exclusion from the study

**Date of first enrolment**

14/10/2023

**Date of final enrolment**

15/12/2023

## Locations

**Countries of recruitment**

Mexico

**Study participating centre****Medica Sur Hospital**

Puente de Piedra No. 150 Colonia Toriello Guerra, Tlalpan

Mexico City

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## Sponsor information

**Organisation**

AB-BIOTICS SA (KANEKA Corp.)

## Funder(s)

**Funder type**

Industry

**Funder Name**

AB-BIOTICS SA (KANEKA Corp.)

## Results and Publications

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

After publication, individual anonymised participant data generated during and/or analysed during the current study will be available upon request from: Jordi Espadaler-Mazo, PhD. (espadaler@ab-biotics.com)

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		26/11/2025	06/01/2026	Yes	No