

# STUDY FACTS

## ***Limosilactobacillus reuteri* ATCC PTA 5289 and DSM 17938 as adjuvants to improve evolution of pharyngitis/tonsillitis in children: randomised controlled trial**

### **Principal Investigator**

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### **Study objective**

To evaluate the safety and efficacy of *Limosilactobacillus reuteri* ATCC PTA 5289 and DSM 17938 in the reduction of the duration and severity of Acute Respiratory Infection (ARI) symptoms.

### **Study design**

The randomised controlled trial included children aged from 6 months to 5 years, with pharyngitis or tonsillitis, who were randomised to receive a probiotic product containing *L. reuteri* ATCC PTA 5289 and *L. reuteri* DSM 17938 or placebo, as drops, taken orally for 10 days as adjuvants to the use of non-steroidal anti-inflammatory drugs.

### **Outcome parameters**

Primary outcomes of the study were duration of ARI symptoms and severity of sore throat. The secondary outcomes were, among others, cough episodes, nasal congestion, number of children receiving antibiotics and absence from daycare.

### **Main results**

The children in the *L. reuteri* group had no fever on day 2 and subsequent days, a significant difference compared to the children in the placebo group ( $p < 0.05$ ). In the beginning of day 3, the severity of sore throat was significantly lower in the *L. reuteri* group than in the placebo group ( $p < 0.05$ ).

Significant differences of days with runny nose, nasal congestion, days of non-planned visits to the medical office or emergency department, levels in tumoral necrosis factor-alpha (TNF-alpha) and related costs of treatment were observed in the *L. reuteri* group compared to the placebo group. The frequency of adverse events was similar between the groups.

### **Conclusion**

*L. reuteri* ATCC PTA 5289 combined with *L. reuteri* DSM 17938 is a safe and effective probiotic adjunct to reduce the symptoms of pharyngitis or tonsillitis in children.

